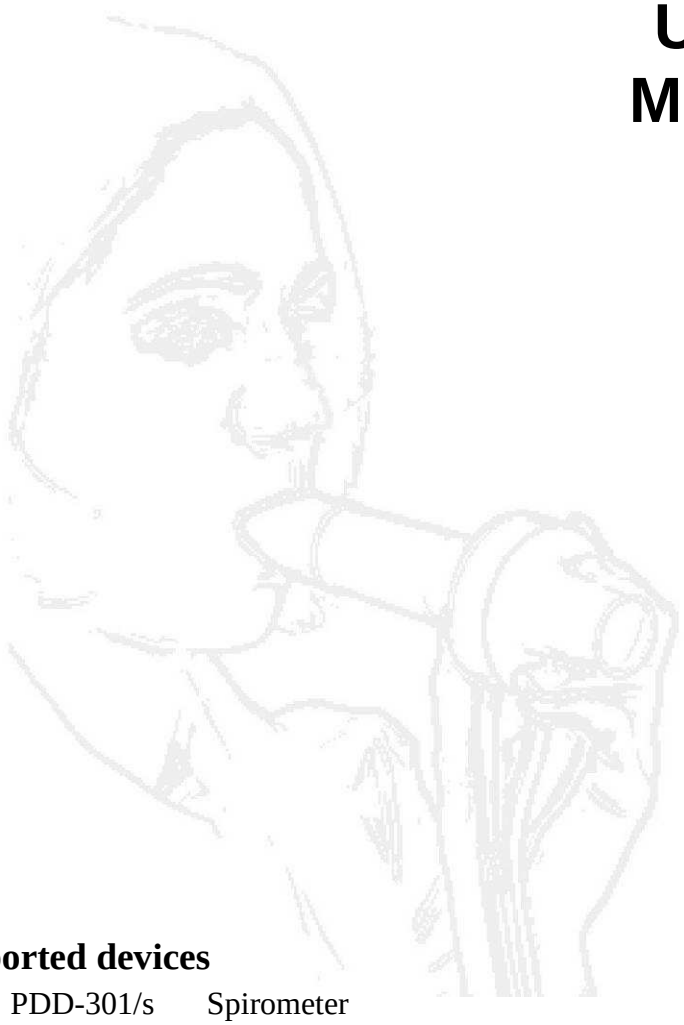
User's Manual



Supported devices

PDD-301/s	Spirometer
PDD-301/r	Rhinomanometer
PDD-301/sco	Breath CO monitor and spirometer
PDD-301/rco	Breath CO monitor and rhinomanometer
PDD-301/p	Dose controlled drug nebulizer
PCD-702	Combo Device
PDT-111/p	Whole-body plethysmograph
PDT-111/d	Diffusion capacity test
PDT-111/pd	Whole-body plethysmograph and diffusion capacity test

Piston Ltd.

1033 Budapest, Szőlőkert u. 4/b

CE 0197

Rev 3.06.02

Nov 30. 2010.

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INTRODUCTION

Devices

Piston Ltd.'s respiratory diagnostics product family contains the following members:

PDD-301/s Spirometer

Measurement operating modes

- Forced inspiration and expiration
- Static vital capacity
- Maximum voluntary ventilation

Design

- Flow meter: PPF-18 PinkFlow, symmetric Pitot tube
- USB computer connection
- Portable design

PDD-301/r Rhinomanometer and Spirometer

Measurement operating modes

- Forced inhalation and exhalation
- Static vital capacity
- Maximum voluntary ventilation
- Nasal respiratory resistance measurement with active anterior and posterior methods

Design

- Flow meter: PPF-18 PinkFlow, symmetric Pitot tube
- USB computer connection
- Portable design

PDT-111/p Whole-body plethysmograph

Measurement operating modes

- Forced inhalation and exhalation
- Static vital capacity
- Maximum voluntary ventilation
- Thoracic gas volume measurement
- Residual volume measurement
- Respiratory resistance measurement
- Respiration work measurement
- Nasal respiratory resistance measurement with active anterior and posterior methods

Design

- Heated flow meter with stainless steel screen
- Hermetically sealed cabin
- USB computer connection

PDT-111/d Diffusion capacity measurement

Measurement operating modes

- Forced inhalation and exhalation
- Static vital capacity
- Maximum voluntary ventilation
- Residual volume measurement
- Transfer factor measurement

Design

- Heated flow meter with stainless steel screen
- Measurement gases: CO and CH4
- USB computer connection

PDT-111/pd Whole-body plethysmograph and diffusion capacity test

Measurement operating modes

- The combined device's measurement operating modes are identical to the PDT-111/p and PDT-111/d devices' measurement operating modes

PDD-301/p Dose controlled drug nebulizer

A medication nebulizer for the all above listed diagnostic devices, which enables phramaco-dynamic measurements

- Dosage distribution
- Respiration phase controlled vaporization
- Built-in compressor
- USB computer connection

PCD-702 Combo Device

The Combo Device is technically equal to a fully functional PDD-301/s Spirometer, a PDD-401 Audiometer plus an IMED Cardiax 12 channel ECG in a single housing.

Symbol annotation

The following symbols indicate which descriptions apply to which device.

S	Spirometer
R	Rhinomanometer
P	Plethysmograph
D	Diffusion capacity test
SA	Combo Device (Spirometer+Audiometer+ECG)

Technical overview

Lung diagnostic device family main parts description:

Flow meter PDD-301/s, PDD-301/r

PPF-18 PinkFlow, symmetric Pitot tube flow meter, which provides pressure difference in proportion with the flow speed.

A differentiate pressure sensor converts the pressure difference to electric signal.

Patient circuit PDT-111/p

The patient circuit ensures device-to-patient connection and contains the following parts:

- Lilly-type heated screen flow sensor
- Shutter magnetic valve
- Metronome

Patient circuit PDT-111/d and PDT-111/pd

The patient circuit ensures device-to-patient connection and contains the following parts:

- Lilly-type heated screen flow sensor
- Shutter magnetic valve
- Metronome
- Demand valve
- Gas sampling line

Plethysmograph cabin PDT-111/p and PDT-111/pd

The closed cabin makes it possible to measure alveolar pressure by non-invasive method through two transfers.

- The cabin has two types of leakage time constants, user selectable depending on measurement method
- The cabin door can only be locked from the out, from the inside it can only be opened
- In case of locking mechanism malfunction, the cabin can be opened from the outside by undoing a few screws

Gas supplying system PDT-111/d and PDT-111/pd D

To determine diffusion capacity the patient must inhale an air mixture containing CO 0.3% and CH4 0.3% gases.

Parts of the gas supplying system:

- High-pressure gas cylinder
- Pressure reductor
- Main valve
- Pressure limiting safety valve
- Demand valve, which ensures gas amount required by the patient's inhalation

Gas analyzer PDT-111/d and PDT-111/pd D

The patient's exhaled has mixture must be sampled and analyzed to determine diffusion capacity.

Parts of the gas analyzer:

- Gas sampling capillary
- PermaPure capillary moisture exchanger to normalize the humidity of the gas samples
- Sampling pump, vibrating membrane design
- NDIR (Non Dispersive Infra Red) multi-channel quick gas analyzer

Environment status measurement module PDT-111/p, PDT-111/d and PDT-111/pd P D

BTPS correction requires the measurement of the following environmental data:

- Environment temperature
- Environment relative humidity
- Atmospheric pressure

Power supply PDT-111/p, PDT-111/d and PDT-111/pd P D

Medical design switching power supply, which enables operating the device from any mains voltage:

- Mains voltage: 90~264 VAC
- Mains frequency: 50~60 Hz

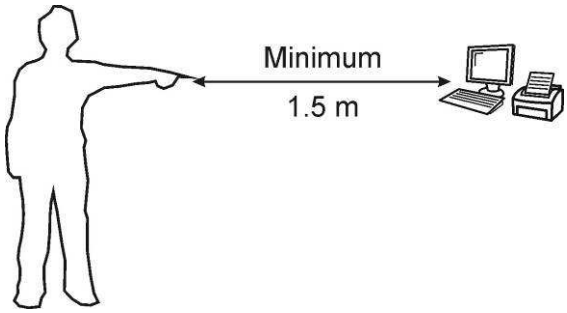
INSTALLATION

Electric shock protection

The electric shock protection instructions in this section must be followed!

Only Piston Ltd., as manufacturer, or its authorized distributor's personnel, or the distributor's representatives may install the lung diagnostics device. The above mentioned companies only accept responsibility for systems installed by them.

Before installing the lung diagnostics devices the personnel must make sure the computer, the monitor and the printer installed as medical electronic devices comply with the standards, for the given country or the user declares concerning this with responsibility.



Information exchange with the computer goes through USB connection. For low leakage current relating to medical devices standards this connection is optically isolated inside the device.

Before shipping we check the device's leakage current. The operator has the opportunity to have the leakage current checked periodically, if he / she finds it necessary.

The system must be installed so the examined person is at least 1.5m away from those devices that are electrically connected to the computer equipment.

Parts of the system (computer, monitor, printer) can only be replaced in case of failure, modification or for any other reason, if the part to be installed has the same electric shock protection conditions as the original one.

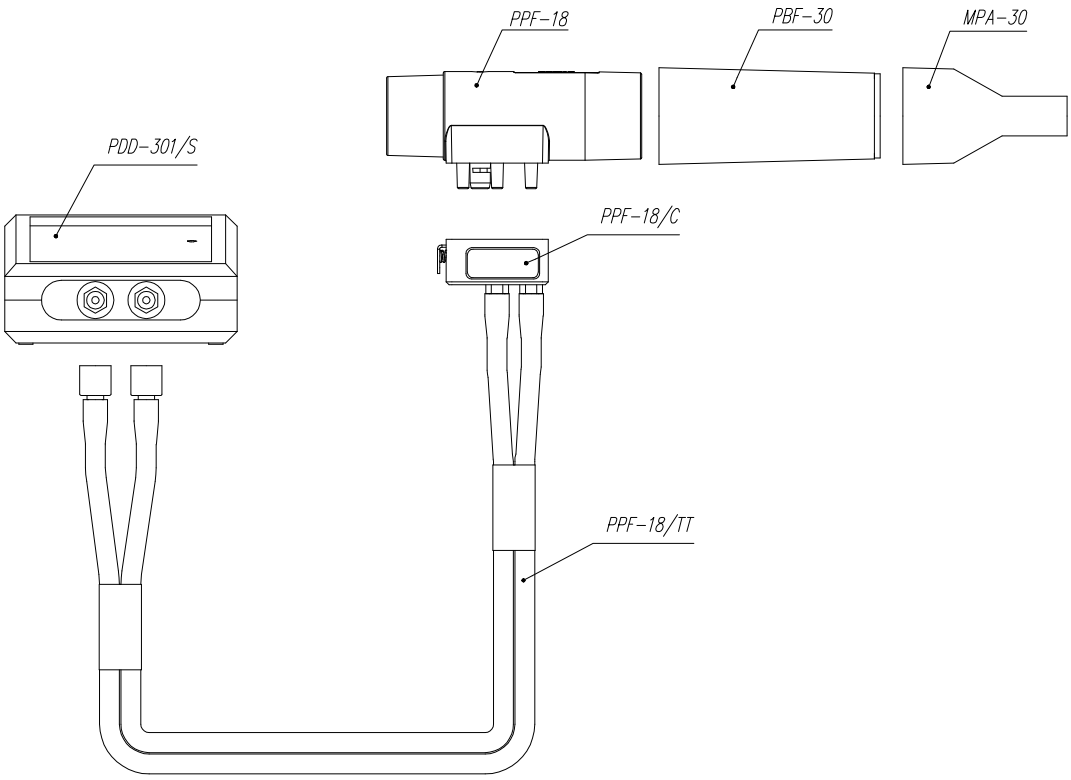
The personnel installing the device will train the operator concerning operation electric shock protection. This training includes the contents of this section. The operator verifies the training in official written form.

Minimum PC configuration

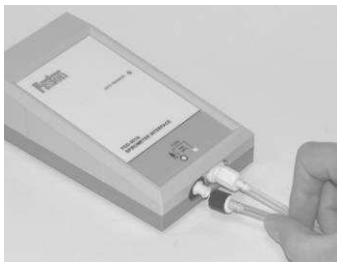
The operation of the lung diagnostics system requires a personal computer with the following minimum configuration:

Description	**Minimum**	**Recommended**
Operating system	Windows XP	
Processor for PDD-301 family	600 MHz	Intel Celeron / Pentium 3 / Core 2 family AMD K6 / Athlon / Duron family
Processor for PDT-111 family	1 GHz	Intel Celeron/Pentium 4 / Core 2 family AMD K6/Athlon/Duron family
Screen resolution	1024×768	1280×1024
Printer	Windows compatible	Colour
Internet connection		For software updates

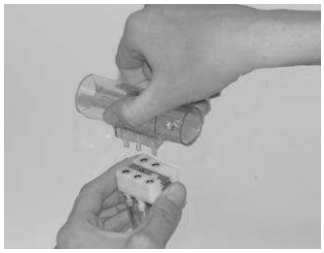
PDD 301/s Spirometer installation



Connect the USB cable to the device and to the PC

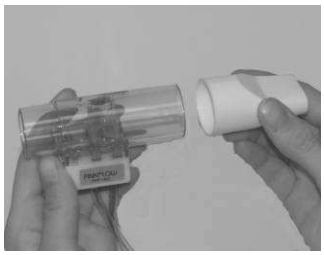


Connect the blue connector of the twin tubing to the blue coded socket indicated with the Flow meter label and the white connector to the white coded socket
For the proper connection the lock should be turned 180 degrees clock wise



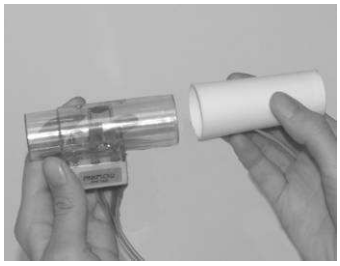
For the connection push the PinkFlow flow meter into the quick connector
For removal push the metal button

The PinkFlow flow meter can be used without bacterial filter as well. In this case a clean PinkFlow meter should be installed prior to each patient.

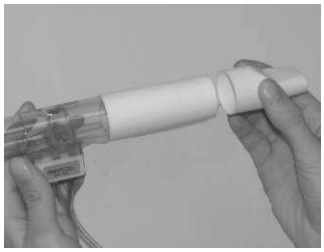


Connect one MPA-30 mouthpiece to bigger diameter end of the PinkFlow flow meter

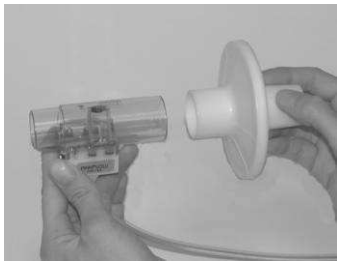
If there is no possibility to provide a clean PinkFlow flow meter prior to each patient you have to use a bacterial and viral filter to avoid cross contamination.
Both PBF-30SU and PBF-100SU bacterial and viral filter can be used.



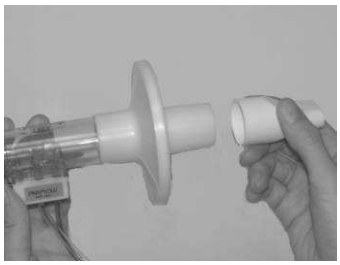
Connect one PBF-30SU bacterial and viral filter to bigger diameter end of the PinkFlow flow meter



Connect one MPA-30 mouthpiece to the bacterial and viral filter

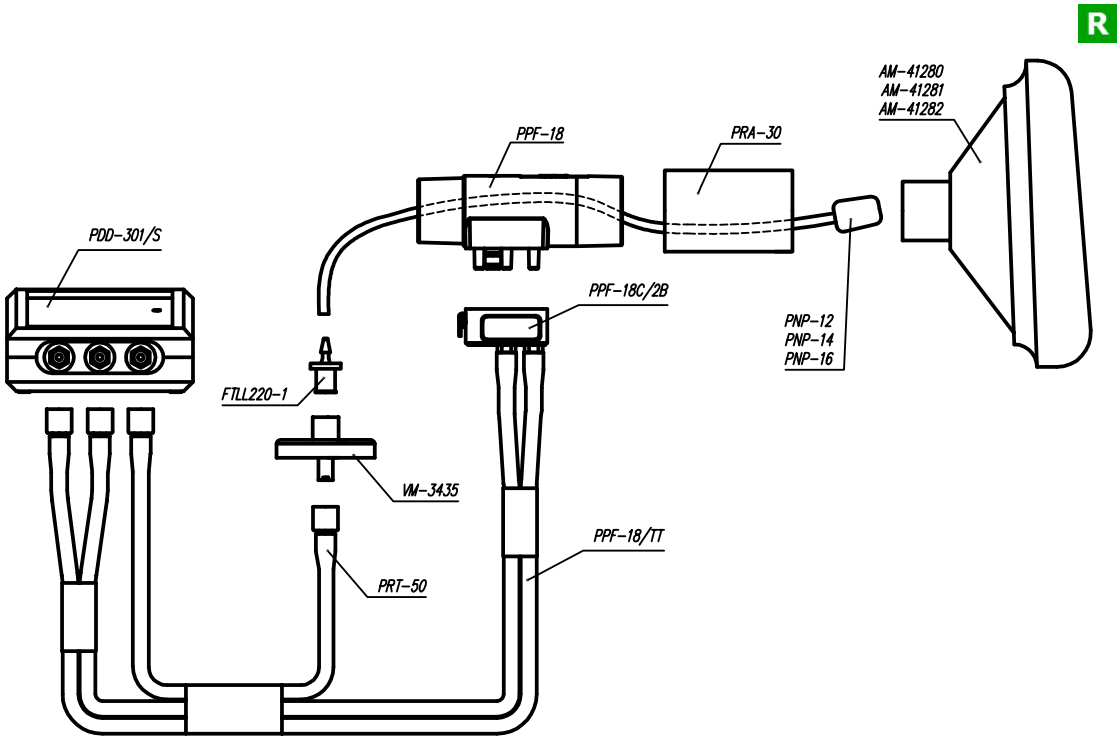


Connect one PBF-100SU bacterial and viral filter to bigger diameter end of the PinkFlow flow meter



Connect one MPA-30 mouthpiece to the bacterial and viral filter

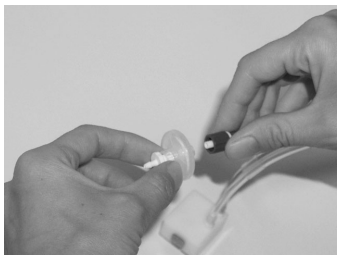
PDD 301/r Rhinomanometer installation



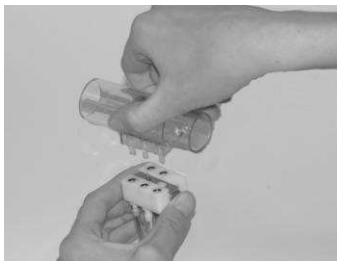
Connect the USB cable to the device and to the PC

Connect the blue connector of the twin tubing to the blue coded socket indicated with the Flow meter label and the white connector to the white coded socket

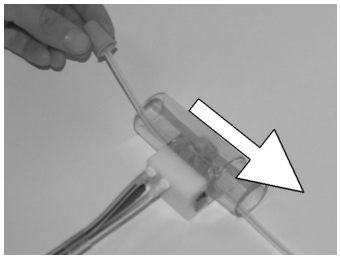
Connect the green connector of the nasal pressure tubing to the green coded socket
For the proper connection the lock should be turned 180 degrees clock wise



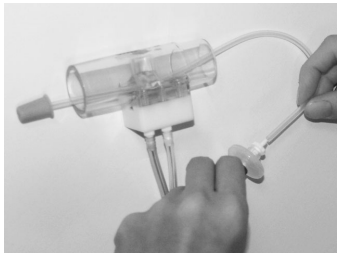
The disc filter of the pressure port prevents the device from the contamination
When the disc filter gets dirty it has to be replaced



For the connection push the PinkFlow flow meter into the quick connector
For removal push the metal button



Select a proper size Nasal probe and lace its tubing thru the PinkFlow flow meter. The plug of the Nasal probe has to face the patient side of the flow meter namely it has to be on the opposite side to the release button of the pneumatic quick connector.



Connect the tubing of the Nasal probe to the barbed fitting of the disc bacterial filter

Warning: When a tubing of the Nasal probe is laced thru the PinkFlow flow meter the sensitivity of the flow meter is modified. This modification is automatically corrected in the Rhinomanometer mode.

Do not use the Nasal probe during any other measurement!

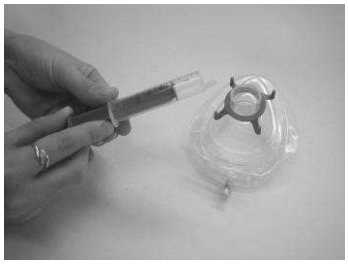
Only the Piston made Nasal probes can be used with the device.

The PinkFlow flow meter can be used only without bacterial and viral filter in Rhinomanometer mode consequently a clean PinkFlow flow meter has to be connected prior to each measurement.

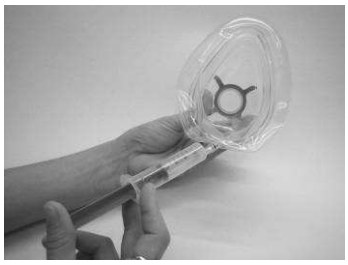
Lace the plug of the Nasal probe thru the adapter of the facial mask and connect the PinkFlow flow meter to the adapter.

Facial mask maintenance

The facial mask's pneumatic cushion may deflate with time. For appropriate fitting the escaped air must be replaced:



Fill a LUER cone-shaped syringe with air



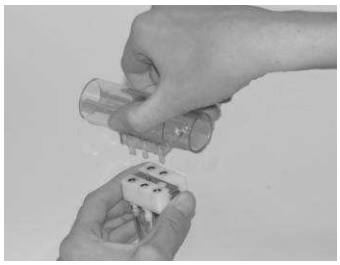
Fit the syringe into the facial mask valve opening, push it in all the way to open the valve. Push the air in

Repeat the previous two steps until the facial mask is properly inflated. Never over inflate as it will not properly fit the face

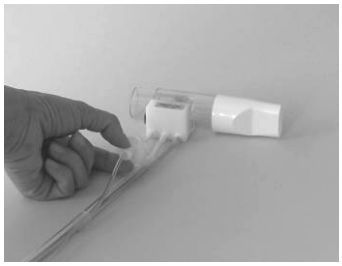
PDD 301/sco and PDD 301/rco Breath CO monitor installation

Connect the USB cable to the device and to the PC

Connect the blue connector of the twin tubing to the blue coded socket indicated with the Flow meter label and the white connector to the white coded socket
Connect the yellow connector indicated with the Gas sample label to the yellow coded socket
For the proper connection the lock should be turned 180 degrees clock wise



For the connection push the PinkFlow flow meter into the quick connector
For removal push the metal button

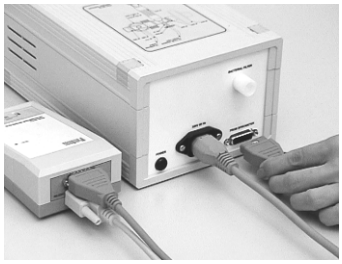


The disc filter of the gas sampling tubing prevents the device from the contamination
When the disc filter gets dirty it has to be replaced

PDD 301/p Dose controlled drug nebulizer installation

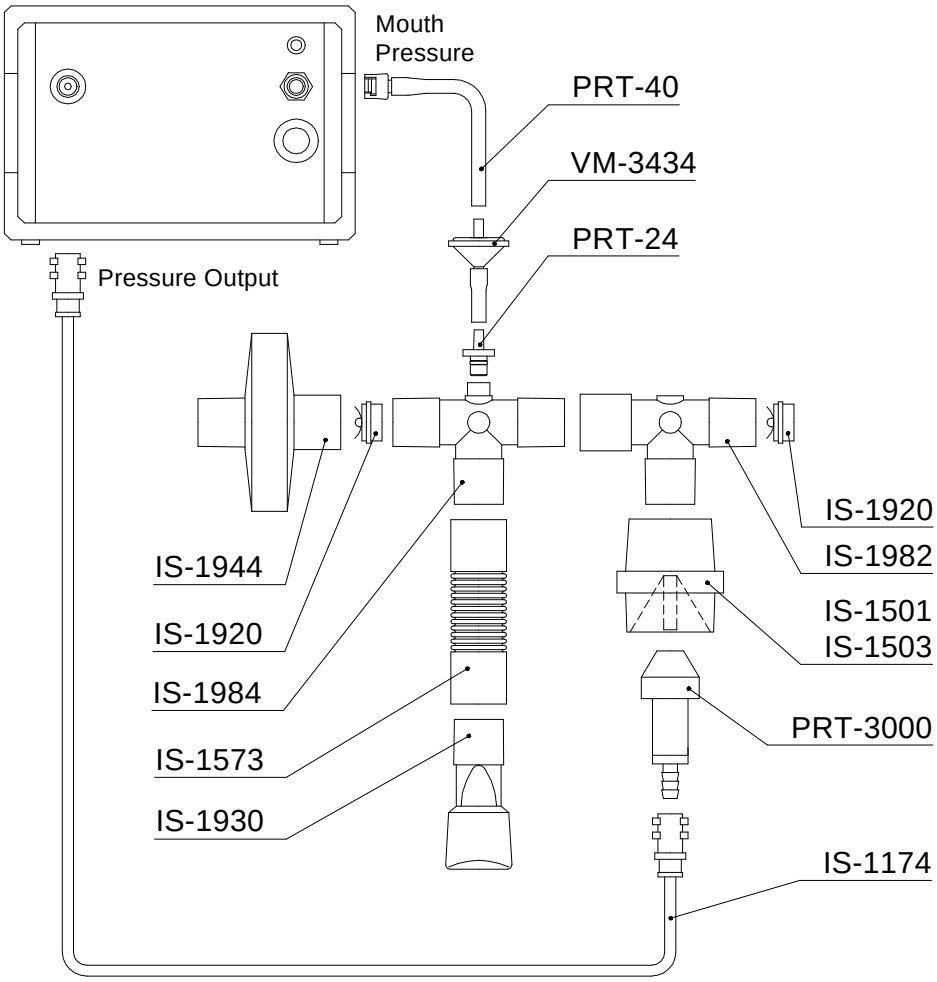
The PDD-301/p Dose controlled drug nebulizer can cooperate with any measurement device of the respiratory device family.

It is operated via the main system software.



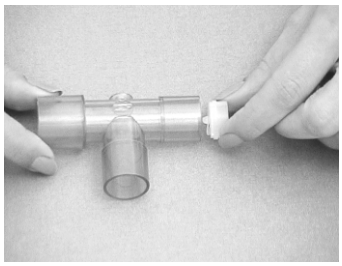
Connect one end of the USB cable to the device, the other end to one of the USB ports in the computer

Installing the nebulizer head:

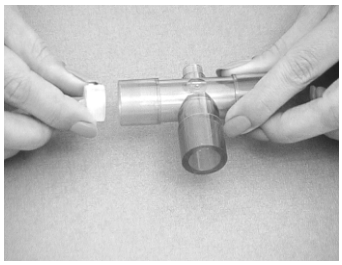


Part number	Description
IS-1944	Bacterial and viral filter
IS-1920	Check valve
IS-1984	T-part with pressure port
PRT-24	Mouth pressure filter fitting
VM-3434	Mouth pressure bacteria and viral filter
IS-1982	T-part
IS-1174	High-pressure tube
IS-1573	Corrugated tube
IS-1930	Mouthpiece
PRT-40	Tygon tube for pressure meter
PRT-3000	One-way valve
IS-1501	Nebulizer pot – green 3,5 micron
IS-1503	Nebulizer pot – purple 1,2 micron

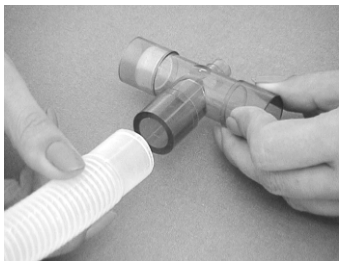
When inserting the check valve pay special attention to the appropriate opening and closing direction. The cone-shaped connection parts must fit tight, paying extra attention to the secure sealing.



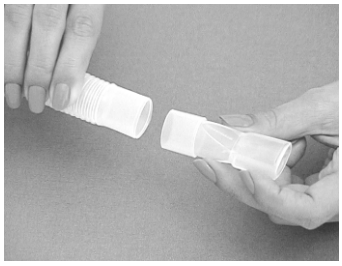
Place one of the check valves into the T-part without the pressure release port



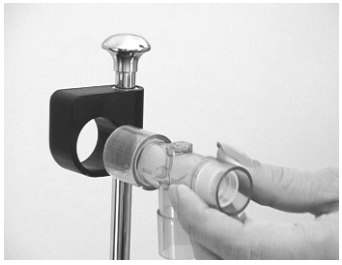
Place the other check valve into the T-part with the pressure port



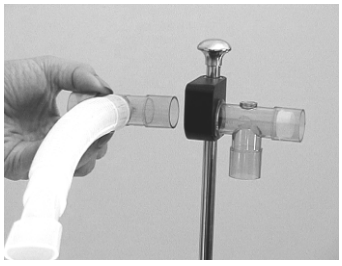
Place the corrugated tube onto the T-part with the pressure port



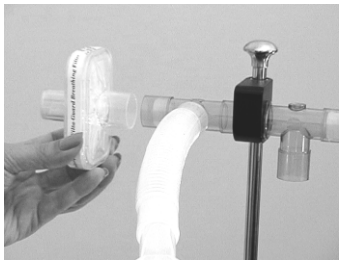
Fit the mouthpiece to the other end of the corrugated tube



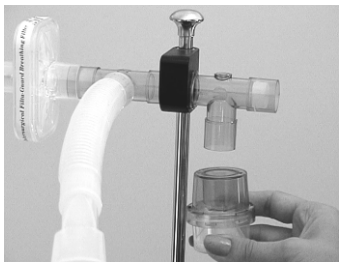
Fit the T-part without pressure port to the stirrup



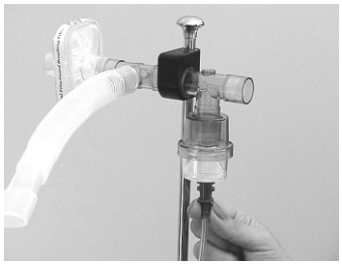
Fit the other T-part into the stirrup



Fit the bacterial and viral filter onto the exhalation side. The filter prevents the exhaled agent to enter the environment

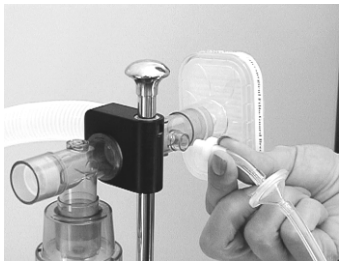


Fit the appropriate colour nebulizer pot.

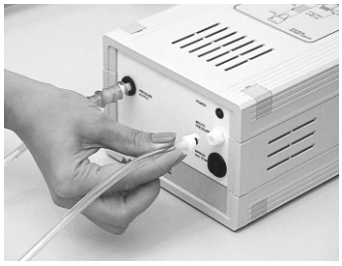


Connect one end of the compressor pneumatic tube to the one-way valve, and connect the one-way valve to the nebulizer head

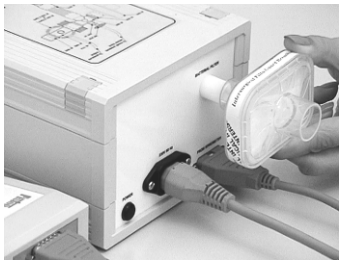
Connect the other end of the mouth pressure tube to the device's MOUTH PRESSURE plug



Connect the mouth pressure tube to the T-part with the pressure port
The mouth pressure sensor's filter protects the device's internal parts



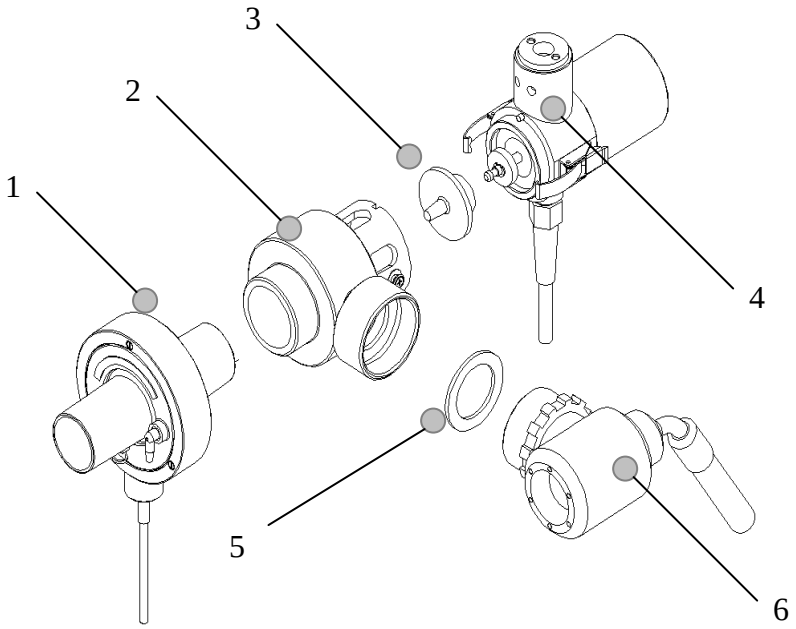
Connect the other end of the mouth pressure tube to the device's MOUTH PRESSURE plug



Insert the other bacterial and viral filter onto the compressor's intake port
This ensures that the compressor is not contaminated

PDT-111/p and PDT-111/d Patient circuit

P D



Item	Part number	Description	Comment
1	FM-15000/HM	Flow sensor	
2		Valve manifold	
3	SV-36	Valve-disc	
4		Measurement head holder with metronome	
5	CV-35/A, B	Demand valve sealing	Only for diffusion capacity test
6	MSAOE LA 96-N	Demand valve	Only for diffusion capacity test

PDT-111/p and PDT-111/pd Cabin placement

P D

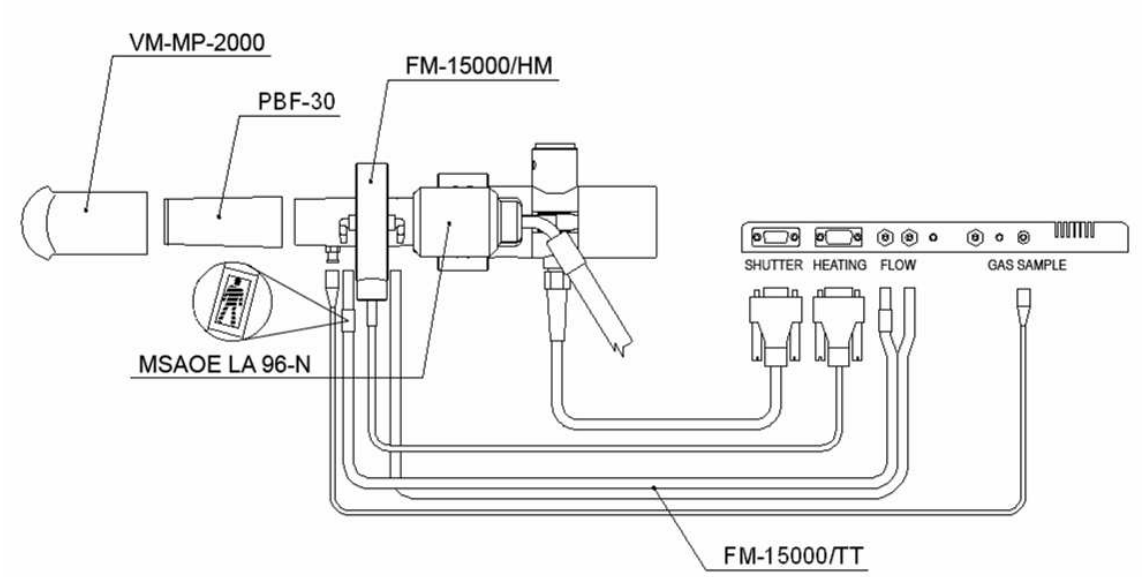
Place the plethysmograph warily. Since extremely small pressure differences have to be measured in the plethysmogram cabin, external interference adversely affect measurement accuracy.

The following have to be taken into the consideration during installation and operation:

- Do not install the device in a draughty place
- There must not be a radiating heat source (radiator, sunny window) within 1 meter
- Air-conditioning unit’s orifice within 1 meter
- Open window or door during measurement

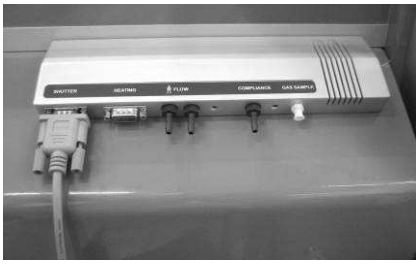
PDT-111/pd Plethysmograph and diffusion capacity test installation

P D



Part number	Description	Comment
VM-MP-2000	Rubber mouthpiece	
PBF-30	Disposable bacterial and viral filter	
FM-15000/HM	Heated metal-screened flow sensor	
FM-15000/TT	Pneumatic twin tube	
MSAOE LA 96-N	Demand valve	Only with diffusion capacity test
PPBF-900	PermaPure capillary with bacterial filter	Only with diffusion capacity test

Measurement head support with metronome



Connect the cable from the measurement head support to the connection labeled **SHUTTER**.

Push the valve-disc up to the magnetic valve shaft (SV-36).

Use the draw latch to fix the cabin valve manifold onto the measurement head support.

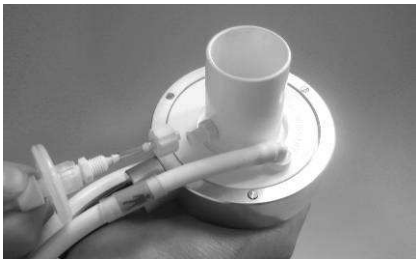
Only for diffusion capacity measurement **D**

Screw the Demand valve onto the valve manifold

Only for diffusion capacity measurement **D**

Connect the Demand valve gas tube to the pneumatic quick connector in the cabin

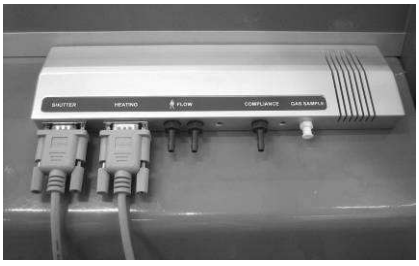
Connect the end of the pneumatic twin tube marked with the patient icon ( ) to the flow sensor
Make sure the side marked with the patient icon ( ) is on the side with gas sampling port



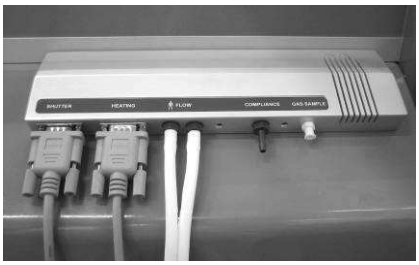
Only for diffusion capacity measurement **D**

Connect the gas sampling capillary to the Luer connector of the flow sensor

Push the heated flow sensor into the valve manifold so the blue patient icon ( ) faces the patient



Connect the flow sensor heating cable to the connector marker **HEATING**



Connect the pneumatic twin tube to the connector marked **FLOW**.
The tube marked with the blue ring must be connected to the connector marked with the patient icon ( )

Only for diffusion capacity measurement **D**

Connect the gas sampling capillary to the connector marked **GAS SAMPLE**.

Connect a new bacterial and viral filter, and a rubber mouthpiece onto the flow sensor before measurement.

Connecting the gas cylinder to the PDT-111/pd

D

Fix the gas cylinder into position

If necessary, replace the gas cylinder sealing ring. Connect the pressure meter reductor to the gas cylinder

Connect the high-pressure gas tube to the cabin's pneumatic quick connector

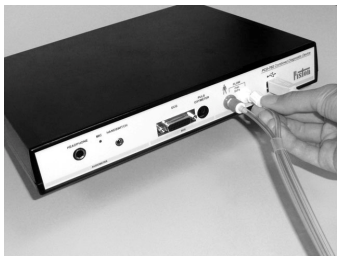
After opening the main valve of the gas cylinder set the secondary pressure to 6 bar

WARNING!
Always turn off the gas cylinder at the end of every shift and in all situations when diffusion capacity measurements are not made for longer periods

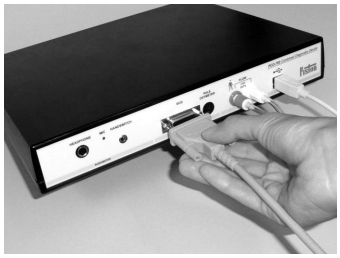
PCD-702 Combo Device

The Combo Device is technically equal to a fully functional PDD-301/s Spirometer, a PDD-401 Audiometer plus an IMED Cardiax 12 channel ECG in a single housing.

Connect the USB cable to the device and to the PC



Connect the Spirometer's patient circuit as described in the Spirometer's documentation



Connect the ECG's patient circuit as described in the ECG's documentation

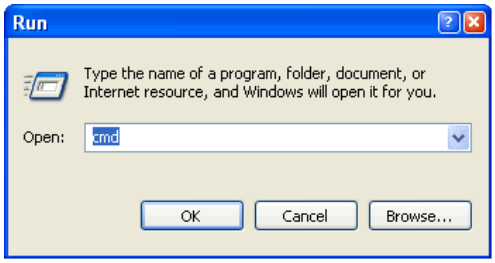
Connect the Audiometer's patient circuit as described in the Audiometer's documentation

Software installation

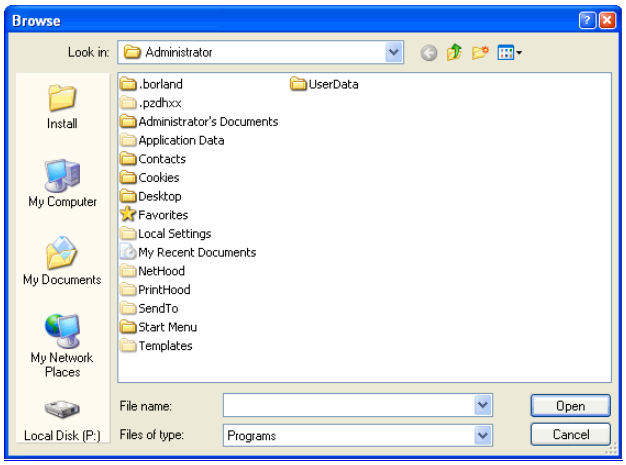
Perform the installation from the included CD.

The most up-to-date version is available from our website:

http://www.pistonmedical.com In the Downloads / Software section.



Click on the **Start** menu and select **Run**

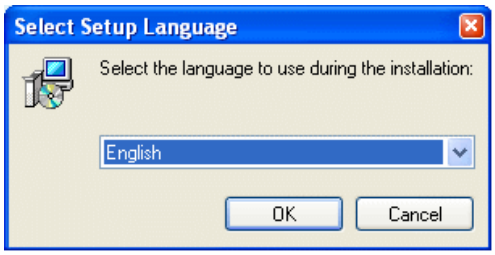


Click on the **Browse** button and select the install program.

When installing from the CD select the CD drive.

Find the pxp_setup.exe file in the Programs folder.

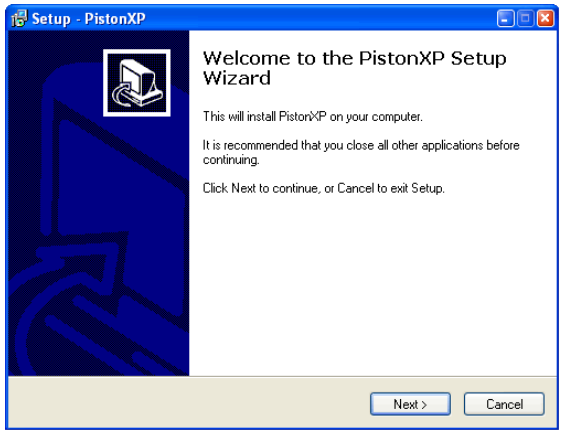
Click **OK**



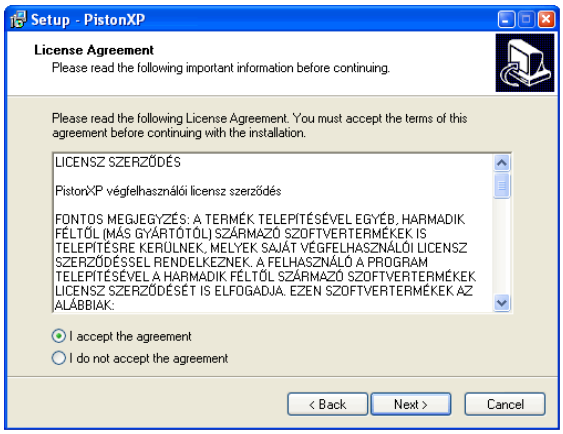
The install program starts

Select the preferred language for the setup and the installed software

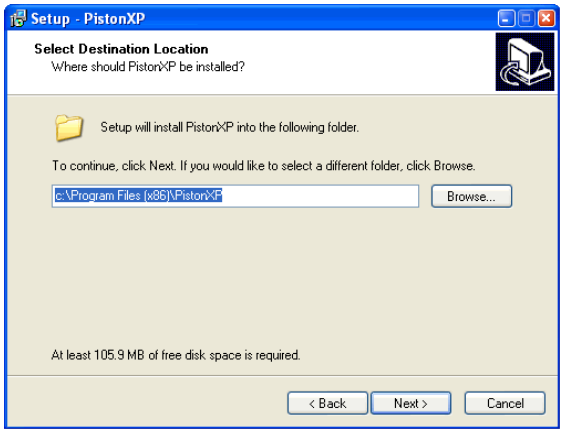
Click **OK**


Setup - PistonXP
Welcome to the PistonXP Setup Wizard
This will install PistonXP on your computer.
It is recommended that you close all other applications before continuing.
Click Next to continue, or Cancel to exit Setup.
Next >
Cancel

A welcome screen appears, just click **Next**

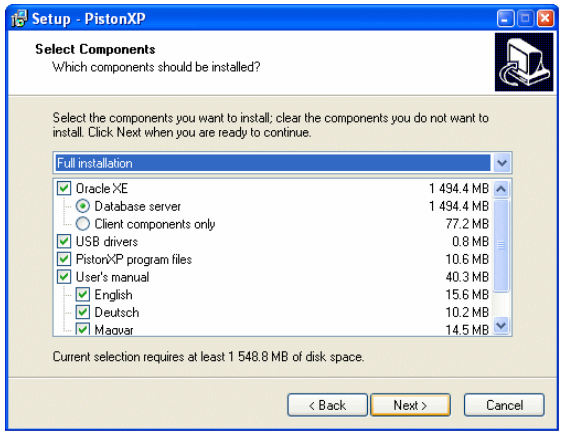

Setup - PistonXP
License Agreement
Please read the following important information before continuing.
Please read the following License Agreement. You must accept the terms of this agreement before continuing with the installation.
LICENSZ SZERZŐDÉS
PistonXP végfelhasználói licensz szerződés
FONTOS MEGJEGYZÉS: A TERMÉK TELEPÍTÉSÉVEL EGYÉB, HARMADIK FÉLTŐL (MÁS GYÁRTÓTÓL) SZÁRMAZÓ SZOFTVERTERMÉKEK IS TELEPÍTÉSRE KERÜLNEK, MELYEK SAJÁT VÉGFELHASZNÁLÓI LICENSZ SZERZŐDÉSSEL RENDELKEZNEK. A FELHASZNÁLÓ A PROGRAM TELEPÍTÉSÉVEL A HARMADIK FÉLTŐL SZÁRMAZÓ SZOFTVERTERMÉKEK LICENSZ SZERZŐDÉSÉT IS ELFOGADJA. EZEN SZOFTVERTERMÉKEK AZ ALÁBBIAK:
I accept the agreement
I do not accept the agreement
< Back
Next >
Cancel

Carefully read the License Agreement, click **I accept the agreement** and click **Next**
If you do not accept the agreement, exit the installation

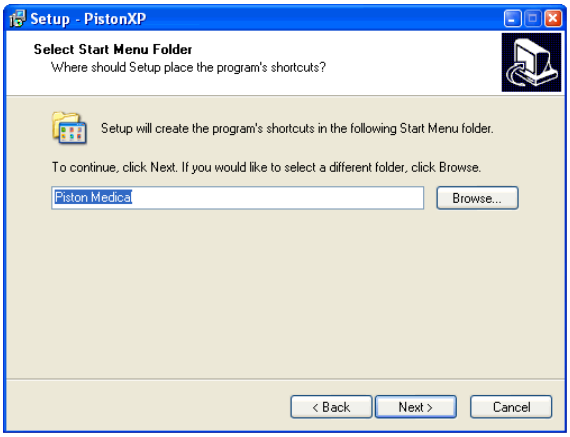

Setup - PistonXP
Select Destination Location
Where should PistonXP be installed?
Setup will install PistonXP into the following folder.
To continue, click Next. If you would like to select a different folder, click Browse.
c:\Program Files (x86)\PistonXP
Browse...
At least 105.9 MB of free disk space is required.
< Back
Next >
Cancel

You can specify the install destination.

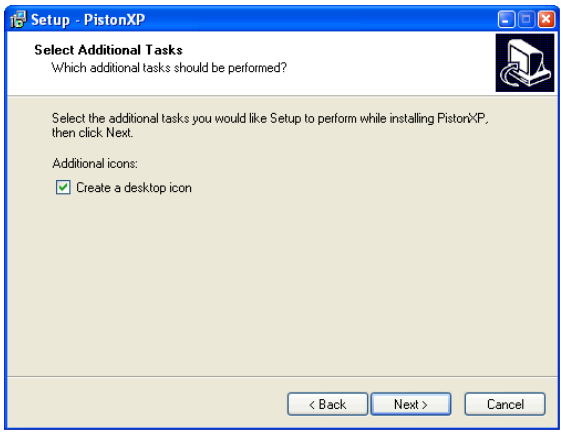
Click **Next**


Setup - PistonXP
Select Components
Which components should be installed?
Select the components you want to install; clear the components you do not want to install. Click Next when you are ready to continue.
Full installation
Oracle XE 1 494.4 MB
Database server 1 494.4 MB
Client components only 77.2 MB
USB drivers 0.8 MB
PistonXP program files 10.6 MB
User's manual 40.3 MB
English 15.6 MB
Deutsch 10.2 MB
Magyar 14.5 MB
Current selection requires at least 1 548.8 MB of disk space.
< Back
Next >
Cancel

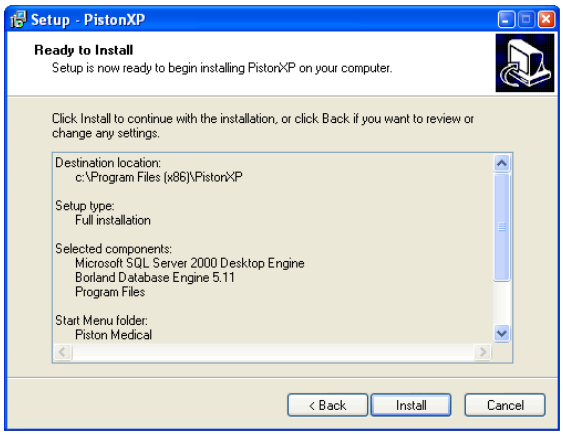
You can select which part of the program to install (experienced users)
Click **Next**


Setup - PistonXP
Select Start Menu Folder
Where should Setup place the program's shortcuts?
Setup will create the program's shortcuts in the following Start Menu folder.
To continue, click Next. If you would like to select a different folder, click Browse.
Piston Medical
Browse...
< Back
Next >
Cancel

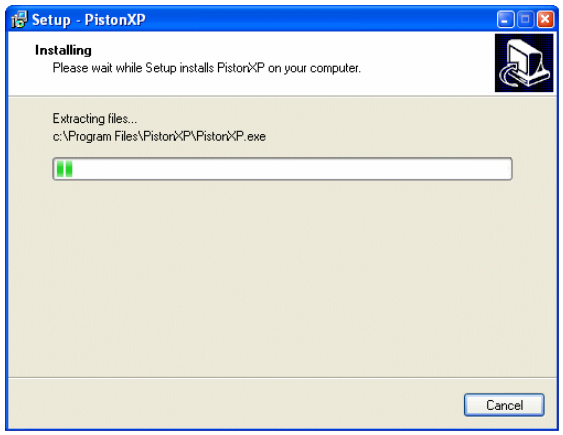
You can enter the name the program appears under in the Start menu (experienced users)
Click **Next**


Setup - PistonXP
Select Additional Tasks
Which additional tasks should be performed?
Select the additional tasks you would like Setup to perform while installing PistonXP, then click Next.
Additional icons:
Create a desktop icon
< Back
Next >
Cancel

You can select whether a PistonXP icon should be created on the desktop (experienced users)
Click **Next**


Setup - PistonXP
Ready to Install
Setup is now ready to begin installing PistonXP on your computer.
Click Install to continue with the installation, or click Back if you want to review or change any settings.
Destination location:
c:\Program Files (x86)\PistonXP
Setup type:
Full installation
Selected components:
Microsoft SQL Server 2000 Desktop Engine
Borland Database Engine 5.11
Program Files
Start Menu folder:
Piston Medical
< Back
Install
Cancel

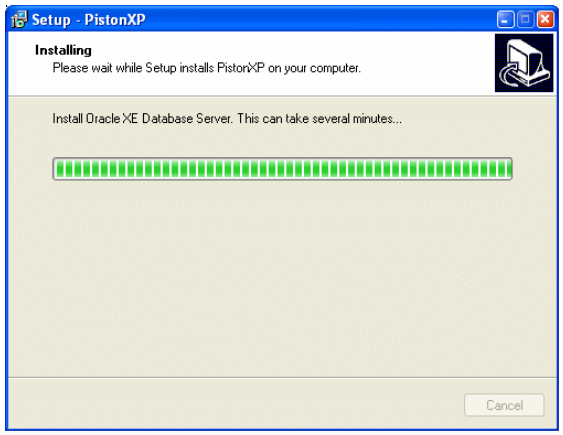
An install summary window appears, and if all settings are acceptable
Click **Install**



The install process begins

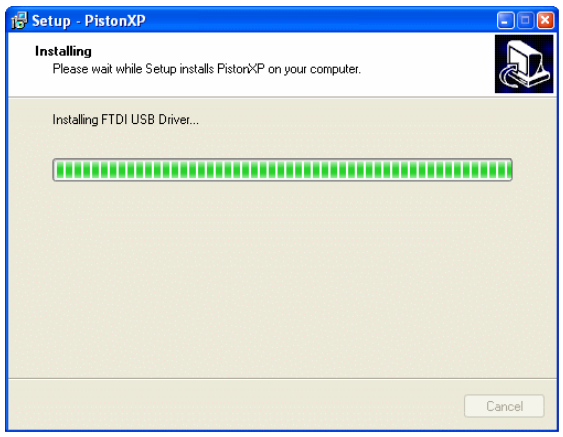
Please wait until it finishes installing the software

After installing the software, external components will be installed also


Setup - PistonXP
Installing
Please wait while Setup installs PistonXP on your computer.
Install Oracle XE Database Server. This can take several minutes...
Cancel

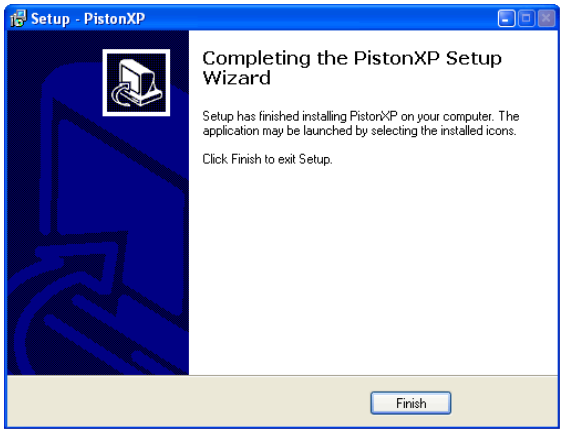
The installation of the Oracle XE Database Server / Client runs in background and the process can take several minutes

Please wait until it finishes installing the software



Finally USB Drivers are being installed

Please wait until it finishes installing the software


Setup - PistonXP
Completing the PistonXP Setup Wizard
Setup has finished installing PistonXP on your computer. The application may be launched by selecting the installed icons.
Click Finish to exit Setup.
Finish

A window indicates the end of the installation

Click **Finish** to close the install wizard

This concludes installation
Start the program
The program automatically detects the connected devices

MAINTENANCE

Device maintenance

Our lung diagnostics devices do not require special maintenance. For continuous reliable operation take care of the following:

- To prevent device contamination and patient cross-contamination, use a new disposable bacterial and viral filter for all patient measurements
- The flow sensor must be contamination free
- The filter elements must be replaced according to instructions
- The PermaPure moisture exchange capillary must be replaced according to instructions
- The tubes must always be dry and cannot be broken

Flow meter maintenance

The flow meter condition and cleanliness affects measurement accuracy.

Cleaning measurement head main parts

The individual patient circuit type installations are described in section Installation (page 8.).

The plastic parts may be disinfected with cold water and appropriate chemicals (for example, Sekusept), and may be used after rinsing and drying.

Cleaning the flow meter

- Unscrew the flow meter
- Clean the measurement screen in ultrasonic cleaner
- After it is completely dried, reassemble the flow meter

Cleaning the pneumatic twin-tubes

- Disconnect the twin-tube from the device and the flow meter
- Rinse the tube
- After it is completely dried, reconnect the tube

Cleaning the medication nebulizer patient circuit

The medication nebulizer patient circuit must be rinsed at the end of each shift. This prevents vaporized material drying into the system.

Breath CO monitor maintenance

The expected life time of the CO sensor is 2 years.

For replacement of CO sensor please contact the local responsible of the Manufacturer!

Disposable accessories

Bacterial and viral filter (PBF-30SU)

The applied bacterial and viral filters are considered to be dangerous waste and must be handled according to valid laws.

Mouthpiece (MPA-30)

The applied mouthpieces are considered to be dangerous waste and must be handled according to valid laws.

Reusable accessories

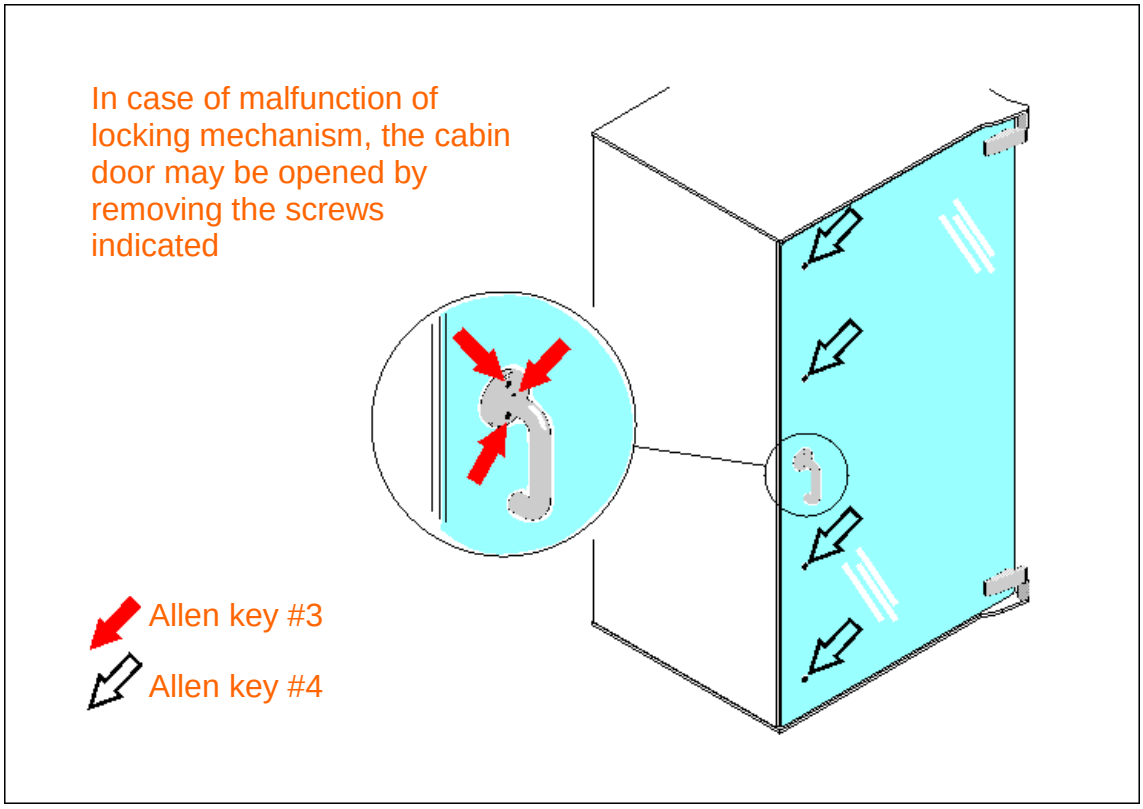
Rubber mouthpiece (VM-MP-2000)

The rubber mouthpiece may be disinfected with a disinfecting solution made of cold water and appropriate chemicals (for example, Sekusept), and may be reused after rinsing.

TROUBLESHOOTING

Escape from the Plethysmograph cabin

In case of malfunction of locking mechanism, the cabin door may be opened by removing the screws indicated on the following image. The required Allen keys are included with the Plethysmograph cabin accessories.


In case of malfunction of locking mechanism, the cabin door may be opened by removing the screws indicated
Allen key #3
Allen key #4

Possible problems

Spirometrics		
Problem	**Diagnosis**	**Solution**
During quiet breathing the Volume(time) curve drifts up or down	After several quiet breaths have the patient remove the mouthpiece The program continues to display the curve. Watch the spirogram for at least 10 seconds	Set Zero again and repeat the measurement. Check that liquid did not get into the flow sensor or the twin-tube leading to it.
The measured values deviate from expected to a considerable extent	The device has to be recalibrated Environmental data must be checked	If the situation does not get better even after recalibration, clean the pneumatic twin tubes and check the flow sensor according to Flow meter maintenance (page 30.) section
Rhinomanometer		
The resistance curves are too steep	The pressure meter's or the nasal plug's pneumatic tube is not connected appropriately, it maybe punctured	Check the pressure tubes The nasal plug, the filter, or the pressure release tube is clogged
The resistance curves are too flat	The device measures the drive pressure to be too high	Check the pressure tubes The nasal plug, the filter, or the pressure release tube is clogged

Medication nebulizer		
Problem	**Diagnosis**	**Solution**
Medication vaporization does not start with inhalation	The device measures the mouth pressure incorrectly	The mouth pressure release tube is either incorrectly connected or clogged The vaporization threshold pressure value is set too high
The patient cannot inhale or exhale, or only with difficultly	One of the two check valves built into the patient circuit (inhalation and exhalation side) is inverted	Assemble correctly the patient circuit according to the section PDD 301/p Dose controlled drug nebulizer installation (page 15.)
Thoracic gas volume measurement		
Resistance and TGV loops appear as vertical lines.	Cabin pressure measurement problem	Check that the cabin door is properly closed The device must be recalibrated and leakage must be checked
Most of the resistance loops are good, but some are distorted	Some sort of pneumatic interference happened during the measurement, for example a window or door was opened	If this is a regular occurrence, find a more suitable place for the cabin.
The shutter does not open at the end of TGV measurement, but loop curve is made	The patient is not trying to breath properly, the inhalation and exhalation attempt is not enough	The shutter only opens after a number of acceptable complete cycles. Perform a new measurement after properly informing the patient.
During TGV measurement the loop curve is completely horizontal	Mouth pressure is not measured	Check the shutter valve-disc status and measurement head assembly must be checked.
Flow sensor temperature is not appropriate	Heating is not operating properly	Check the HEATING connection and cable
The metronome does not emit a light signal or the shutter does not close	Faulty connection	Check the SHUTTER connection and cable
After plethysmograph measurement the curve disappears and there are no measurement results	The measurement stopped because the cabin door opened during measurement	The measurement must be stopped with the **[**Done**]** button before opening the door.

Diffusion capacity test		
Problem	**Diagnosis**	**Solution**
The patient cannot inhale gas mixture	The gas supply system is faulty	The following must be checked: • Gas cylinder main valve is open • There is enough pressure in the gas cylinder • The secondary pressure is set to 6 bar
Software		
Cannot find a patient.	Too many search criteria.	Enter less search criteria.
The patient's data cannot be loaded with the [**Load all**] button.	The patient probably has more than 8 measurements.	At most 8 measurements must be selected.
The patient's data cannot be loaded with the [**Selected**] button.	Not a single measurement has been selected.	If there is only one measurement in the list, use the [**Load all**] button.
When making PRE/POSTreport, the program only prints previous data loaded from the database.	The new measurement has not been stored.	The measurement must be stored with the [**Store**] button before printing.

THE PROGRAM'S MAIN FUNCTIONS

Available examinations

Parallel measurements

The program makes it possible to perform eight different measurements in all measurement modes. All eight measurements' data can be stored, and reloaded later.

Forced exhalation and inhalation

S R P D

The most widely applied method for dynamic lung function test.
Detailed description may be found in the Measurement modes (page 82) section.
In this operating mode the device measures the following parameters:

FVC **Forced Vital Capacity**

Expired volume after full inspiration at the highest possible flow

FEV*0,5 **Forced Expiratory Volume 0,5 sec**

The amount of air exhaled in the first 0.5s during forced exhalation

FEV*1,0 **Forced Expiratory Volume 1,0 sec**

The amount of air exhaled in the first 1.0s during forced exhalation

FEV*0,5/IVC

The ratio of FEV*0.5 and the static vital capacity

FEV*0,5/FVC

The ratio of FEV*0.5 and the forced vital capacity

FEV*1,0/IVC

The ratio of FEV*1.0 and the static vital capacity

FEV*1,0/FVC

The ratio of FEV*1.0 and the forced vital capacity

PEF **Peak Expiratory Flow rate**

Highest flow during forced exhalation

FEF*25-75% **Forced mid-Expiratory Flow rate**

The average volume-flow speed calculated for the middle half of forced exhalation

MEF*75% **Forced Expiratory Flow at 75% lung volume**

Flow when 75% of the forced vital capacity is still in the lung

MEF*50% **Forced Expiratory Flow at 50% lung volume**

Flow when 50% of the forced vital capacity is still in the lung

MEF*25% **Forced Expiratory Flow at 25% lung volume**

Flow when 25% of the forced vital capacity is still in the lung

FET **Forced Expiratory Time**

The duration of forced exhalation.

MTT **Mean Transit Time**

The average leaving time from the lung of gas molecules during forced expiration

FIVC **Forced Inspiratory Vital Capacity**

Inspired volume after full expiration at the highest possible flow

FIV*0,5 **Forced Inspiratory Volume 0,5 sec**

The amount of air inhaled during the first 0.5 seconds of forced inhalation.

FIV*1,0 **Forced Inspiratory Volume 1,0 sec**

The amount of air inhaled during the first 1.0 seconds of forced inhalation.

PIF **Peak Inspiratory Flow rate**

Highest inhalation flow speed during forced inhalation

FIF*25-75% **Forced mid-Inspiratory Flow rate**

The average flow calculated for the middle half of the forced inhalation.

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/volume loop

Static vital capacity

S R P D

The most widely used method for the static lung function test.
Detailed description may be found in the Measurement modes (page 82) section

In this operating mode the device measures the following parameters:

IVC **Inspiratory Vital Capacity**

Total inspired volume after a full expiration

IRV **Inspiratory Reserve Volume**

The inspiration reserve volume is volume, what the patient can inhale from the average inhalation endpoints of quiet breathings

ERV **Expiratory Reserve Volume**

The expiration reserve volume is volume, what the patient can exhale from the average exhalation endpoints of quiet breathings

TV **Tidal Volume**

The average volume moved during quiet breathing

SVC **Slow Vital Capacity**

Total expired volume after full inspiration

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/volume loop

Maximal voluntary ventilation

S R P D

A rarely used dynamic lung function test.
Details may be found in the Measurement modes (page 82) section.
In this operating mode the device measures the following parameters:

MVV **Maximal Voluntary Ventilation**

The maximum respiratory volume measured during voluntary respiration, calculated for one minute

MVV*f **Maximal Voluntary Ventilation Frequency**

The maximum respiratory frequency measured during voluntary respiration, projected for one minute

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/volume loop

Breath CO measurement

S R P D

The device insures the measurement of breath carbon monoxide concentration. It is inevitable in the smoking cessation program.

Details may be found in the Measurement modes (page 82) section.

In this operating mode the device measures the following parameters:

CO ppm **Breath CO concentration**

%COHb **Carboxyhemoglobin %**

SVC **Slow Vital Capacity**

The Slow Vital Capacity is the volume which was exhaled slowly by the patient after a total inspiration.

The following graphs are displayed during measurement:

- Volume/time curve
- CO ppm/time

Plethysmograph measurement

P

Complex lung function test to measure the mechanical parameters of the respiratory system.
Details may be found in the Measurement modes (page 82) section.
In this operating mode the device measures the following parameters:

TLC **Total Lung Capacity**

Total lung capacity

TGV **Thoracic Gas Volume**

Thoracic gas volume

RV **Residual Volume**

Residual volume

RV/TLC **Residual Volume/Total Lung Capacity**

The ratio of residual volume and total lung capacity

Raw **Resistance of Airways**

Airway resistance

Rin **Resistance of Airways at Inspiration**

Airway resistance during inhalation

Rex **Resistance of Airways at Expiration**

Airway resistance during exhalation

Req **Equivalent Resistance**

Equivalent airway resistance

sRaw **Specific Resistance of Airways**

Specific airway resistance

sRin **Specific Resistance of Airways at Inspiration**

Specific airway resistance during inhalation

sRex **Specific Resistance of Airways at Expiration**

Specific airway resistance during exhalation

Gaw **Conductance of Airways**

Airway conductance

Gin **Conductance of Airways at Inspiration**

Airway conductance during inhalation

Gex **Conductance of Airways at Expiration**

Airway conductance during exhalation

sGaw **Specific Conductance of Airways**

Specific airway conductance

sGin **Specific Conductance of Airways at Inspiration**

Specific airway conductance during inhalation

sGex **Specific Conductance of Airways at Expiration**

Specific airway conductance during exhalation.

BF **Frequency of Breathing at Resistance Measurement**

Breathing frequency during resistance measurement.

W **Work of Breathing at Resistance Measurement**

Breathing work during resistance measurement.

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/P_{alv} Resistance loop
- P_{mouth}/P_{cab} TGV loop

Diffusion capacity test

D

Complex lung function test for the measurement of oxygen bounding capacity of the lung.
Detailed information may be found in the Measurement modes (page 82) section.

In this operating mode the device measures the following parameters:

TLC **Total Lung Capacity**

Total lung capacity

IVC **Inspiratory Vital Capacity**

Total inspired volume after a full expiration

IRV **Inspiratory Reserve Volume**

The inspiration reserve volume is volume, what the patient can inhale from the average inhalation endpoints of quiet breathings

ERV **Expiratory Reserve Volume**

The expiration reserve volume is volume, what the patient can exhale from the average exhalation endpoints of quiet breathings

TV **Tidal Volume**

The average volume moved during quiet breathing

RV **Residual Volume**

Residual volume

RV/TLC **Residual Volume/Total Lung Capacity**

The ratio of residual volume and total lung capacity

FRC **Functional Residual Capacity**

Function residual capacity

FRC/TLC

The ration of Function residual capacity and total lung capacity

Single-Breath:

Tlco **Transfer factor of the lung for CO**

The lung's transfer factor for carbon monoxide

The SI unit of measurement: mmol/min/Pa

Dlco **Transfer factor of the lung for CO**

The lung's transfer factor for carbon monoxide.

The imperial unit of measurement: ml/min/mmHg

Klco **Transfer coefficient of the lung for CO**

Transfer coefficient.

BHt **Breath hold time**

Effective time breath hold time

Intra-Breath:

Tlco IB **Transfer factor of the lung for CO**

The lung's transfer factor for carbon monoxide

The SI unit of measurement: mmol/min/Pa

Dlco IB **Transfer factor of the lung for CO**

The lung's transfer factor for carbon monoxide

The imperial unit of measurement: ml/min/mmHg

Klco IB **Transfer coefficient of the lung for CO**

Transfer coefficient

Auxiliary parameters supporting evaluation of measurements

WOV **Wash-Out Volume**

Wash-out volume

FACH4 **Expiratory concentration CH4**

Exhaled CH4 concentration

FACO **Expiratory concentration CO**

Exhaled CO concentration

CCCH4 **Calibration constant of CH4 channel**

CH4 channel calibration constant

CCCO **Calibration constant of CO channel**

CO channel calibration constant

GSL **Gas Sample Lag**

Gas sampling time displacement

CH4 IB L **CH4 concentration by IB on Left side**

Exhaled CH4 concentration at the left side of gas sampling window during Intra-Breath measurement

CH4 IB R **CH4 concentration by IB on Right side**

Exhaled CH4 concentration at the right side of gas sampling window during Intra-Breath measurement

CO IB L **CO concentration by IB on Left side**

Exhaled CO concentration at the left side of gas sampling window during Intra-Breath measurement

CO IB R **CO concentration by IB on Right side**

Exhaled CO concentration at the right side of gas sampling window during Intra-Breath measurement

The following graphs are displayedduring measurement:

- Volume / time curve
  with CH_4, CO, CO_2 gas concentration functions
- Flow/volume loop

Maximal respiratory pressure P D

The measurement of the respiration muscles' maximum strength.
Detailed information may be found in the Measurement modes (page 82) section.

In this operating mode the device measures the following parameters:

PE_{max} Maximal expiratory pressure

Maximum expiratory pressure.

PI_{max} Maximal inspiratory pressure

Maximum inspiratory pressure.

The following graphs are displayed during measurement:

- Volume / time curve

Compliance

P D

The measurement of compliance of the lungs

Detailed information may be found in the Measurement modes (82. page) section.

In this operating mode the device measures the following parameters:

Cdyn **Dynamic Compliance**

Dynamic Compliance of lungs

Edyn **Dynamic Elastance**

Reciprocal ratio of the Dynamic Compliance

Cstat **Static Compliance**

Quasi static compliance of lungs

Estat **Static Elastance**

Reciprocal ratio of quasi Static Compliance

Wcomp **Work of Breathing at Cdyn measurement**

Viscous work of breathing during Dynamic Compliance measurement

ReqComp **Equivalent Resistance**

Equivalent resistance

Parameters listed below are calculated only when the value of the TLC was measured before of the Compliance measurement at TGV or Diffusion capacity test mode:

Cdyn/TLC **Dynamic Compliance/Total Lung Capacity**

Ratio of Dynamic Compliance and TLC

Cstat/TLC **Static Compliance /Total Lung Capacity**

Ratio of Static Compliance and TLC

Cdyn/FRC **Dynamic Compliance/ Functional Residual Capacity**

Ratio of Dynamic Compliance and FRC

Cstat/FRC **Static Compliance/ Functional Residual Capacity**

Ratio of Static Compliance and FRC

Cdyn/TGV **Dynamic Compliance/Thoracic Gas Volume**

Ratio of Dynamic Compliance and TGV

Cstat/TGV **Static Compliance/Thoracic Gas Volume**

Ratio of Static Compliance and TGV

Rhinomanometry

R P

Measuring the nose airway resistance.
Detailed information may be found in the Measurement modes (page 82) section.

In this operating mode the device measures the following parameters:

Flow (50 Pa)

The flow speed at 50 Pa drive pressure.

Flow (75 Pa)

The flow speed at 75 Pa drive pressure.

Flow (100 Pa)

The flow speed at 100 Pa drive pressure.

Flow (150 Pa)

The flow speed at 150 Pa drive pressure.

Flow (300 Pa)

The flow speed at 300 Pa drive pressure.

The following graphs are displayed during measurement:

- Volume/time curve
- Flow/P_{Ch} Resistance loop

Provocation test

The complete pharmaco-dynamic test is fully supported by the dose controlled drug nebuliser.

Thanks to the exact dosage control variations of the lung function parameters can be followed up as a function of inhaled agent.

More detailed description can be found at the Measurement modes (82. page) chapter.

Safety precautions

- The dose controlled drug nebuliser can be used only by the specially trained personnel
- Use only water solvent agent (pH: 2,5 – 4,0).
  If the solvent's chemical properties out of this range please contact the manufacturer of the patient circuit: Intersurgical Ltd. (Crane House, Molly Millars Lane, Wokingham, Berkshire RG41 2RZ, England, Tel: +44-1734-795579).
- Provocation test can be proceeded only at the institutions which have all the necessary human and objective conditions of resuscitation
- It is prohibited to use the drug nebuliser in continuous mode
  The maximal continuous working period is 15 seconds and afterwards a 30 second idle period is requested
- Usage of the drug nebuliser requests constant surveillance
- Upon completing a provocation session a bronchial dilution is strongly recommended.

Electrocardiographyy

The software is able to launch and to transfer patient data to the external ECG software Cardiax. So the user is able to maintence a single database while using the services of two different applications.

System comparison table

	PDD-301/spf	PDD-301/rpf	PDD-301/sco	PDD-301/o	PDT-111/p	PDT-111/d	PRE-101
	Spirometer	Rhinomanometer	Breath CO monitor	Oscillometer	Whole body plethysmograph	Diffusion capacity test	Ergospirometer
PinkFlow* flow-meter	+	+	+	+	+	+	+
Forced ex and inspiration	+	+	+	+	+	+	+
Static vital capacity	+	+	+	+	+	+	+
Maximal voluntary ventilation	+	+	+	+	+	+	+
Nasal resistance		+	optional	+	optional		
Breath CO monitor			+				
Impulse oscillometry				+			
Thoracic gas volume					+		
Airway resistance					+		
Work of breathing					+		
Compliance					optional		
Diffusion capacity					optional	+	
Ergospirometry							+
ECG 12 leads							+
Weight	220 g	220 g	420 g	2,5 kg	200 kg	5,5 kg	4,5 kg
Size	150 * 82 * 45 mm	150 * 82 * 45 mm	190 * 138 * 68 mm	260 * 155 * 160 mm	1680 * 925 * 790 mm	320 * 200 * 240 mm	320 * 200 * 140 mm
Power supply	USB port	USB port	USB port	90 – 260 VAC 50/60 Hz	90 – 260 VAC 50/60 Hz	90 – 260 VAC 50/60 Hz	90 – 260 VAC 50/60 Hz

USER INTERFACE

S R P D

Icons

Main window

Open patient database

Open comment opinion editor

Open lung function test sub-menus

Open external ECG Software

Health Level Seven (HL7) and GDT import and export functions

Open report editor, printing

Exit the program

Main window – Lung function test

Open calibration measurement window. The checkmark indicates that all connected devices are calibrated.

Open calibration window. The exclamation point indicates that one or more connected device needs to be calibrated.

Forced vital capacity (FVC)

Inspiratory vital capacity (IVC)

Maximal voluntary ventilation (MVV)

Rhinomanometry

Thoracic gas volume and Resistance measurement

Compliance measurement

Diffusion capacity test

Maximum inspiratory and expiratory pressure

Provocation test

Breath carbon monoxide monitoring

Manual

Patient database

Clear patient quick search fields

Enter new patient

Modify patient data

Store entered / modified data

Cancel changes

Load all measurements from the selected meeting(s)

Load selected measurements

Health Level Seven (HL7) import and export functions

Settings

Set institute data

Doctor records

Devices' settings connected to the PC

Program operation related settings

Display graphs and other program parts

Maintenance, safety backup related settings

Reference value calculating algorithms

List of parameters to be displayed

Service panels

Enter new doctor

Modify doctor's data

Store entered / modified data

Cancel changes

Accept changes and close Options panel

Measurement windows – Lung function test

Start measurement in at FVC, IVC, MVV, TGV, TLC measurement

Start gas mixture inhalation

Close shutter for respiratoric pressure measurement

	Start drug nebulization
	Do a solution after provocation test
	Measure left nostril resistance
	Measure right nostril resistance
	Start Resistance loop recording (if the measurement already started and the patient breaths quietly)
	Start Dynamic Compliance loop recording (if the measurement already started and the patient breaths quietly)
	Prepare Static Compliance loop recording (if the measurement already started and the patient breaths quietly)
	Start Static Compliance recording
	Finish measurement (in case of successful measurement)
	Abort measurement (partial results are lost)
	The measurement is technically correct
	The measurement is most likely technically incorrect
	The icon in the summary table indicates the active curves, the specific measurement’s curve is also displayed
	Indicates questionable curves The curves appear dashed
	The program does not store curves marked like this and they do not appear on the graph either
	Store active and questionable curves, measurement and their parameters
	Mark all curves as active
	Mark the three best curves as active, hide all other curves
	Effectively delete the selected curve

List of Lung function Parameters

Instructions

PRE/POST

Warnings

Setup

Animation

Miller Quadrant

Report editor

Print preview for lung function tests

Print preview for compliance test

Print preview for rhinomanometer

Print preview for provocation test

Print preview for audiometry

Print preview for calibration

Print selected measurement results

Store a report as PDF document or image

Close Report editor

Calibration

Start calibration

Skip specific phase during plethysmograph calibration, continue from the next step

Abort calibration

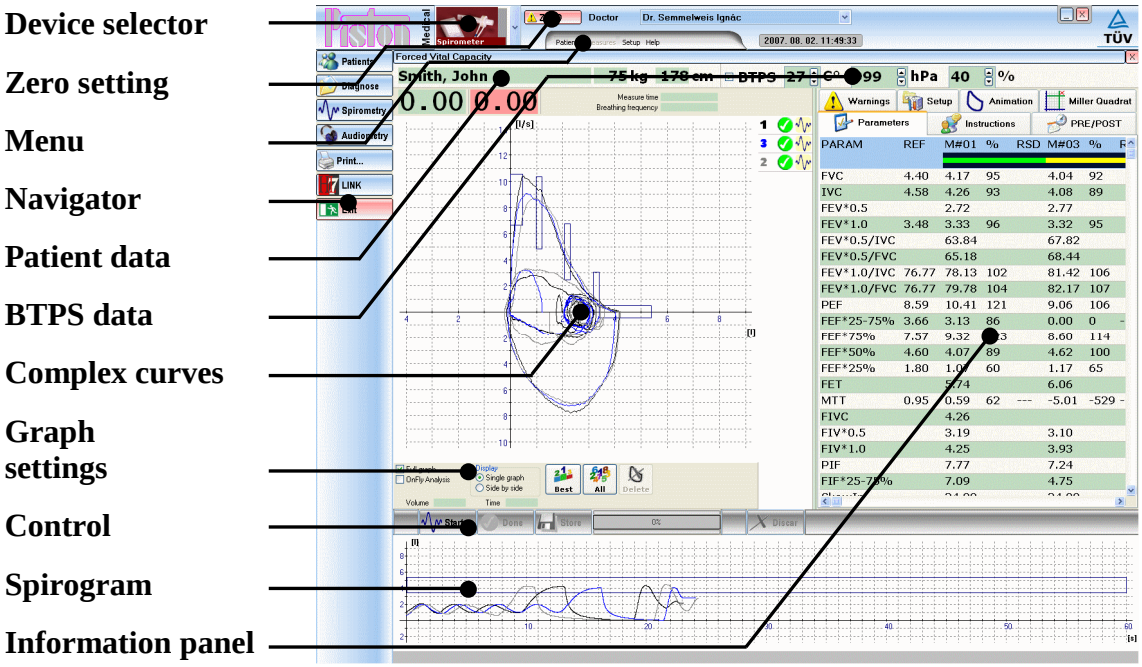
Store measured results

Print calibration report

User interface general design

S R P D

The following image shows the general design of the measurement screens. The individual measurement windows may differ from each other but the main controls are identical.



Device selector

Select the device to be used from the drop down list.
This is necessary if, for example, you own a Plethysmograph and a Spirometer, and would like to perform IVC measurement.

Zero setting

Runs manual Zero setting of the selected device
Without manual Zero setting the system automatically sets zero before all measurements

Menu

The program's general main menu, which contains the grouped basic functions.

Navigator

Controls that group the basic phases of daily routine.

Patient data

Contains the most important measurement data for the patient selected from the database.

BTPS data

These are the environment data measured by members of the PDT-111 device family. If you only own the PDD-301 device, this is where you can set the individual values manually.

Comlex curves

The more complex curves of the individual measurement operating modes. For example, in case of FVC measurement, the flow-volume loops, in case of Plethysmograph measurement Resistance and TGV loops.

Graph settings

This is where you can set graph display modes. These settings are also available on the Options panel, details may be found in the Graph settings (page 55) section.

Control

This filed contains the basic control functions during the measurement. The appropriate Function buttons are shown in square brackets:

- Start measurement **[F3]**
- Start special measurement section **[F4]**
- Finish measurement after a successful measurement **[F5]**
- Stop measurement, abort measurement (for example, in case of malfunction) **[ESC]**
- Store, print

Spirogram

Volume – time graph, which monitors the patient's breathing during the measurement.

Information panel

This section contains information, settings, functions:

- Current measurement parameter list
- PRE/POST settings and parameters
- Measurement related warnings, error messages
- Measurement instructions

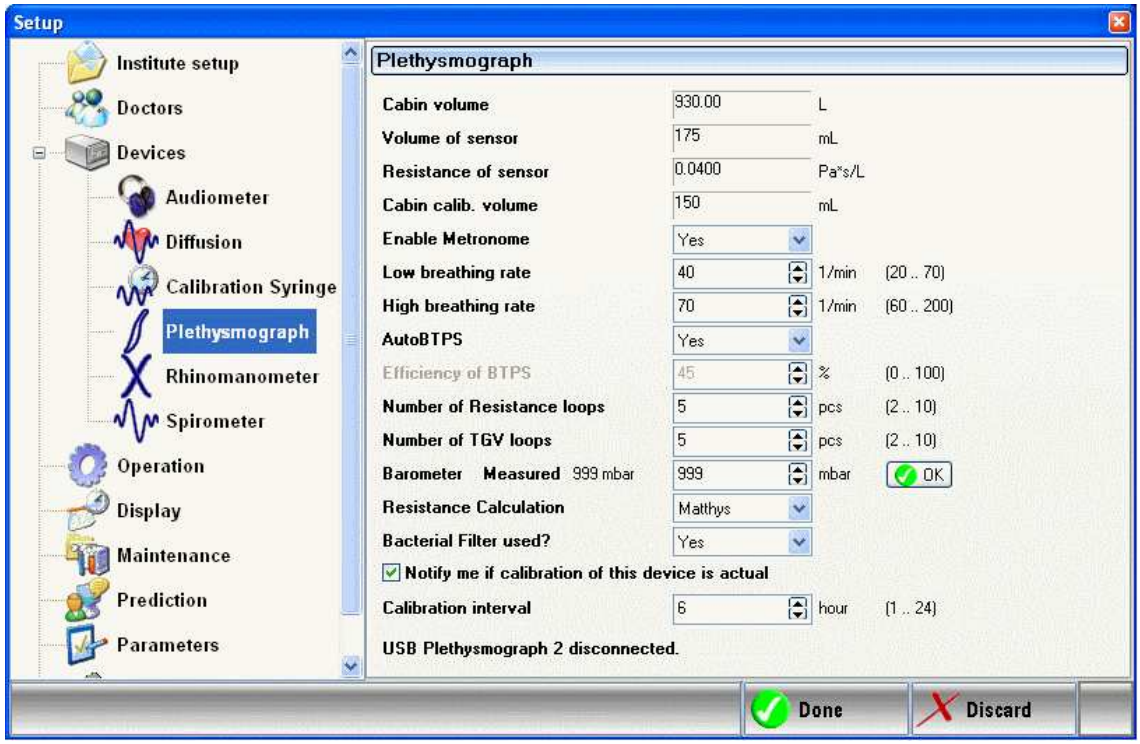
SETTINGS

S R P D

The **Setup/Options** menu item allows customization of the system.

Settings that can be changed during measurement are also available in the **Setup** tab of the measurement windows.

Program settings appear grouped on the left side.



Institute data

You can enter the following information at the **Setup/Options/Institute setup** menu item:

Institute name, Site address, Mailing address, Phone number, Fax number, Web page, E-mail address.

This data appears in the header of the printed report.

Doctor’s data

The doctor’s data can be entered at the **Setup/Options/Doctors** menu item.

New doctor

Press the **[New Doctor]** button to enter data for a new doctor.

Complete the fields.

Make sure that two doctors cannot have the same identifier.

Press the **[Save]** button to store the entered data.

Modify data

Select the doctor from the **[Doctor's** name**]** drop down list whose data you would like to modify.

Click the **[Modify]** button.

Change the desired fields.

When done, press the **[Save]** button.

You will see feedback about the success of the data storage.

If you do not wish to store the entered data, press the **[Discard]** button.

About deleting …

To preserve consistency and for future searches, it is not possible to delete from the database.
All diagnosis has traces in the database.

Language selection

You can select the program's language in the **Setup/Options/Operation** menu item.

All supported languages are displayed in English and in the specific language as well.

Select the language you would like to use.

Patient identification format

You can enter the patient identification format in the **Setup/Options/Operation** menu item.

Format descriptions may be found in the Appendix II. (page 172) section.

Graph settings

Graph displays may be set in the **Setup/Options/Display** menu item.

Graph scheme

You can select the graph color settings:

- Dark background, bright lines
- Bright background, dark lines
- Same as printed (white background)

Raster

The grid may be enabled or disabled on the graph

Show curves

It can be selected for several same type measurements:

- The diagrams appear in one coordinate system.
- All the diagrams appear in different coordinate systems.

Visible part of the curve

For easier overview curve sections unrelated to the evaluation can be hidden.

OnFly Analysis

When this function is enabled, the program monitors the patient's breathing during measurement, separates normal breathing from deep exhalations and inhalations.

Active curves after measure

In the **Setup/Options/Operation** menu item those curves can be selected which will be automatically indicated as active ones after each measurement:

- Just the best measure
- First three
- All measurements

Curve magnification

Click on any graph with the right mouse button.

Select the required size from the menu that appears.

The following magnifications are available:

Resistance measurement: 0.5×-, 1×-, 2×-

Other measurements: 0.5×, 1×, 2×, 3×, 5×

Reference values

The desired algorithm may be selected in the **Setup/Options/Prediction** menu item:

- ECCS – European Community for Coal and Steel
- Knudson
- Cotton & Dust
- Crapo-HSU
- Österreichisch

To turn it off, select the **No reference** values option.

Displayed parameters

In the **Setup/Options/Parameters** menu you can enter which parameter to display on the screen and which one to print.

Devices

Part of the parameters are for system data that can seriously effect measurement accuracy.
You can view these parameters through the user interface, but they cannot be modified.
Only professionals can modify these data in the PistonXP.ini file.

Measuring the environmental status

If you have any member of the PDT-111 device family, the device automatically measures the environmental data necessary for BTPS correction:

- air pressure
- temperature
- humidity

You can select in the **Setup/Options/Operation/Source of environment** info menu which device's environmental data the system should use:

- USB diffusion
- USB Plethysmograph
- Automatic

In case of automatic option

- The device calculates with the environment data measured in the cabin during Resistance and TGV measurement.
- During all other lung function test the system uses the environment data measured by the diffusion capacity meter outside the cabin.

Calibration Syrigne

S R P D

You can set the calibrating pump volume at the **Setup/Options/Devices/Calibration** Syringe menu

Number of calibrating cycles

S R P D

The number of calibrating cycles with the calibration pump may be set in the **Setup/Options/Devices/Calibration** Syringe menu:

- Minimum: 2
- Maximum: 20
- Recommended: 10

Spirometer

Select the **Spirometer** group in the **Setup/Options/Devices** menu.

The system senses the spirometer connection to the USB port in 2 seconds.

Calibration time interval

You can set how often the device should remind you of the need for calibration

Rhinomanometer

Select the **Rhinomanometer** group in the **Setup/Options/Devices** menu.

The system senses the rhinomanometer connection to the USB port in 2 seconds.

Calibration time interval

You can set how often the device should remind you of the need for calibration.

Plethysmograph

Select the **Plethysmograph** group in the **Setup/Options/Devices** menu.

The following device operation related settings are available:

Enable Metronome

You can turn the light and sound signal of metronome on or off.

Low breathing rate

The plethysmograph cabin has two selectable leakage time constants.

Low breath frequency means less stress for the patient, but thermal compensation takes longer.

High breathing rate

High breath frequency means more stress for the patient, but thermal compensation happens sooner.

AutoBTPS

If enabled, resistance loops are automatically closed

Efficiency of BTPS

If AutoBTPS option is off, this is where you can set the theoretical lung model BTPS correction effectiveness.

Default value: 45%

Balance time

This is where you can set the waiting time after closing the cabin's door to the beginning of the very first TGV measurement in order to reach the adequate thermal balance in the cabin

Number of Resistance loops

This is where you can set the number of Resistance loops the device should record in one measurement.

Number of TGV loops

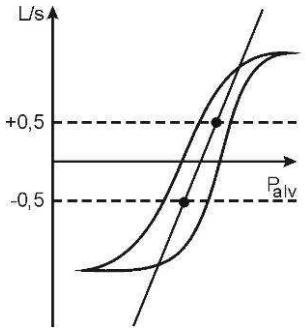
This is where you can set the number of breaths the shutter should close.

Barometer calibration

It is possible to exactly set the barometer measuring environmental pressure. Enter the exact environmental pressure value and click the **[OK]** button.

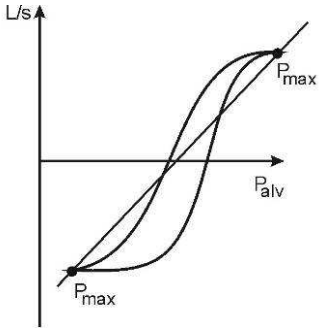
Resistance Calculation

This is where you can set the algorithm used to calculate Resistance loop slope.



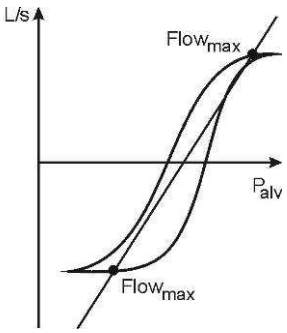
Method by Matthys

Resistance loop is intersected with ±0.5 l/s flow value and place the steepness indicating line on the geometric bisecting points of the horizontal intersections



Method of Peak pressure

We place the steepness indicating line on the peak value points of the pressure measured in the cabin



Method of Maximum flow

We place the steepness indicating line on the maximum flow points

Calibration time interval

You can set how often the device should remind you of the need for calibration.

Diffusion capacity meter

Select the **Diffusion** group in the **Setup/Options/Devices** menu.

The following device operation related settings are available:

CH4 concentration

Original methane concentration of the test gas mixture

CO concentration

Original carbon monoxide concentration of the test gas mixture

Wash out volume (WOV)

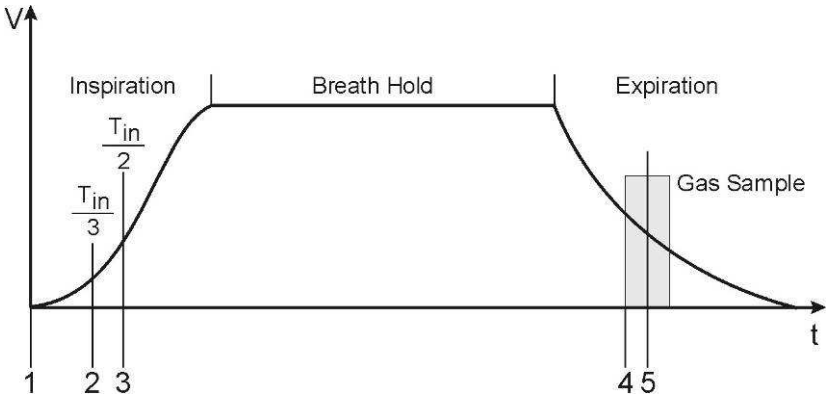
The volume the device releases from the start of expiration until the beginning of gas analysis.

Breath hold time (BHt)

The period of breath holding, or closing the shutter.

BHt calculation method

Since diffusion in the lung starts from the beginning of inhalation and lasts till the end of expiration, the system offers several algorithms to calculate the effective diffusion time:



Ogilvie method

Period start: Start inhalation (1)

Period end: Start gas sampling (4)

Jones and Meade method

Period start: Start inhalation 1/3 (2)

Period end: Middle of gas sampling period (5)

Epidemiologic Standardisation Project method

Period start: Middle of inhalation period (3)

Period end: Start gas sampling (4)

Barometer calibration

It is possible to exactly set the environment pressure measuring barometer. Enter the exact environmental pressure value and press the **[OK]** button.

Calibration before all measurement

You can select to have automatic Zero setting and automatic calibration of gas analyzer before each test

Recommended option.

Using the shutter

You can select to have the shutter closed during breath holding.

If the shutter is closed, the patient has to make sure to hold the breath and not to press the shutter, because this can increase alveolar pressure and change the level of diffusion.

If the shutter is open, the patient has to make sure not to inhale nor exhale when holding the breath, because this changes the gas concentration in the lung and effects the measurement accuracy.

Limit values during breath holding

If you select the **Shutter close** option, you can enter the limit value for mouth pressure fluctuation, beyond which the device emits a warning.

If you select the **Shutter open** option, the inhaled volume limit value during breath holding cannot exceed ±200 ml.

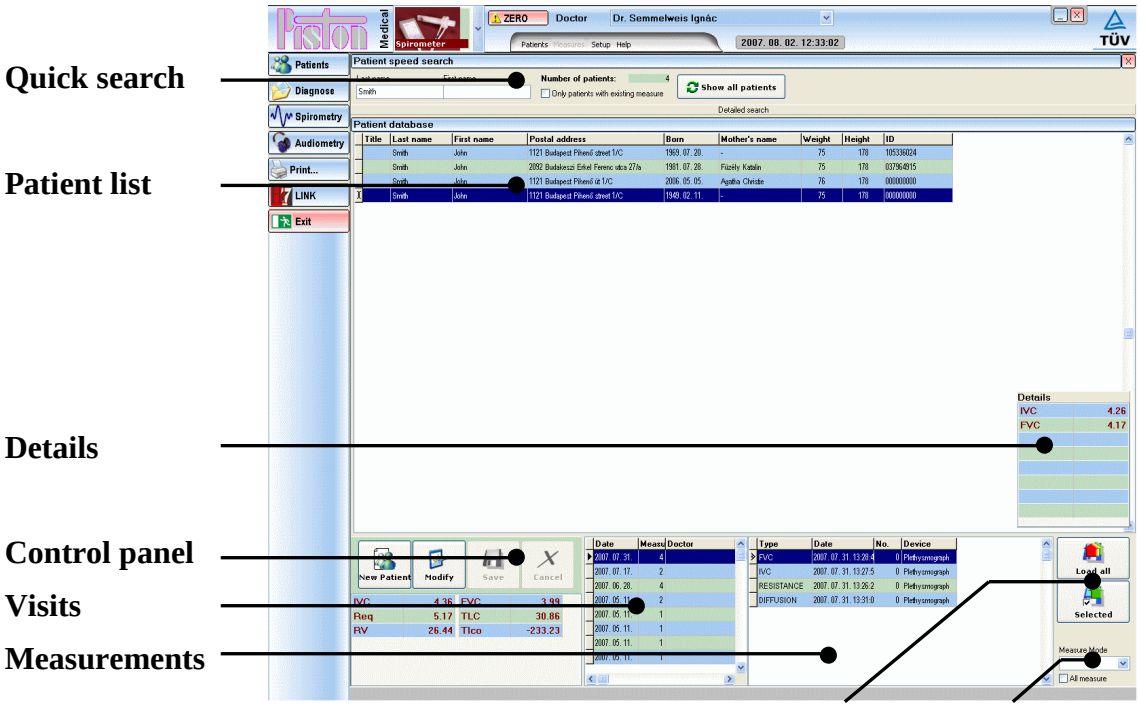
Calibration interval

You can set how often the device should remind you of the necessity to calibrate.

PATIENT DATABASE

User interface overview

Main window



Quick search

Helps find a patient.

Patient list

A list of patients meeting the search criteria.

Details

Displays the selected patient's most important parameters for the selected measurement.

Control panel

Basic database operations: enter new patient, modify patient data, store.

Visits

Dates of previous visits.

Measurements

A list of measurements for the selected date or measurement type.

Load

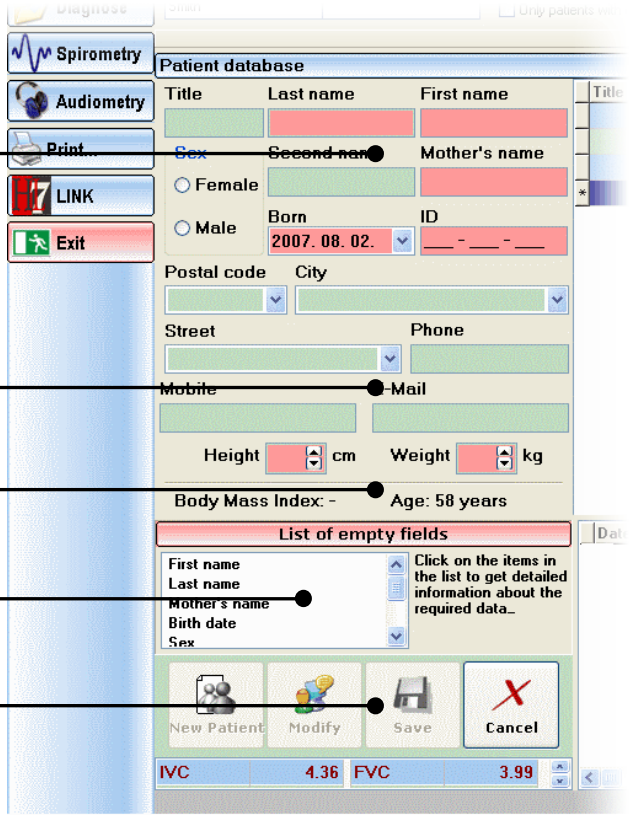
Control buttons to display the selected measurements.

Measurement selection

Measurements may be listed according to measurement type as well.

Data input form

Content of the Data input form can be set in the menu **Setup** / **Options** / **Display** / **Contents of Patient's** Datasheet*



Identifying data

Group of data essentially identifying the patient: Name, date of birth, social security number, sex, etc.

Accessibility

Patient's accessibility: Address, phone numbers, e-mail address.

Body mass index (calculated value)

The patient's current body weight index: square of the height of the patient in meter divided by body weight

List of incomplete fields

A list of fields that either have to be completed and are still empty, or that have been filled out incorrectly.

Control panel

Basic database operations: new patient, modification, store.

*You have to close and re-open Patient's Database to apply changes

Patient's personal data

The program can store an arbitrary number of patients.

Pink fields indicate fields that have to be completed.

Anthropometrics data

You have to enter the patient's body mass and height

These data are required to calculate reference value

The database stores the body mass and height of the patient for each visit, so changes may be followed in time.

New patient

To enter a new patient, press the **[New Patient]** button. Complete the fields and make sure that two patients cannot have the same identifier.

To store the patient, press the **[Save]** button.

You will receive feedback about the success of data storage.

If you do not wish to save the data, press the **[Cancel]** button.

Modify data

Select the patient to modify

Click on the **[Modify]** button

After modification press the **[Save]** button

You will receive feedback about the success of data storage

If you do not wish to save the modified data, press the **[Cancel]** button

About deleting …

To preserve consistency and for future searches, it is not possible to delete from the database. All diagnosis has traces in the database.

Finding a patient in the database

The top section of the patient database window is the search block.

You can search based on several criteria. When those criteria change, the program automatically lists the patients meeting the updated criteria

Normal search

Search only based on the patient's family and surname.

Enter the patient's name or part of it.

Detailed search

Click the **[Detailed search]** button.

You can refine the search criteria in the window:

- patient‘s sex
- date of birth with interval
- address or part of it
- doctor
- identifier (social security number)

Viewing previous measurements

All previous measurements can be reloaded, so reports can be printed at anytime.

Viewing previous measurements

To reload previous measurements:

- Select the patient
- Select the visit by date
- If you only wish to view the results of certain measurement mode select the one from the list
- Select required measurements

If you wish to see all measurement results of a selected visit, click the **[Open]** button
If only certain measurements are important; click them while holding the CTRL button down
After selection click on the **[Open]** button!

If you wish to include further measurements to the report click the **[Patient database]** button to reopen the Patient database.

Select further measurements and click the **[Add measure]** button to include them to the report.

WARNING:
You can only simultaneously load eight measurements of the same mode.
For this reason, the [Load all] button is not always available.

PRE/POST evaluation

To load the data for all previous visits, check the **[All measurements]** checkbox.

This displays a patient's all previous measurements sorted according to the following:

- Date
- Measurement mode
- Measurement results quality

Select the results of at least two identical measurement mode, for example two FVC measurements.

Load the data as mentioned earlier.

PRE/POST measurements are detailed in the PRE/POST section (Page 122).

Comment field for patients

Comments may be entered about the patients even for every visit. All comments are stored separately in the database and may be retrieved individually.

To enter a comment:

- Open the Patient database
- Selected the desired patient
- Click the **[Diagnose]** button to open the text editor window
- Select the **[Patient]** operating mode from the list
- Enter the comment
- Press the **[Store]** button to store the comment

Previous diagnosis

All previous comments about the patient may be retrieved from the **[History]** list.

The currently entered text is not lost when viewing a previous diagnosis.

To display the currently entered text again, select the **[Patient]** option from the list of operating modes again.

CALIBRATION

After turning the device on and entering the BTPS data, calibration is recommended for maximum measurement accuracy.

Calibration is recommended when starting a new shift, after flow sensor disinfections or replacement.

IMPORTANT

If work environment conditions (temperature, air pressure, humidity) change significantly, re-calibration is recommended.

Flow meter calibration

S R P D

The flow meter volume calibration ensures maximum accuracy and is an efficient way to check the proper operation.

It is possible to perform measurements without calibration but at least 5% additional error must be taken into account.

Connecting the flow meter

Connect the patient side, the bigger diameter side of the PinkFlow flow meter of the Spirometer or the Rhinomanometer directly to the calibrating pump.

Connect the patient side of the flow meter of Plethysmograph or Diffusion capacity test directly or with the included coorrugated tube to the calibrating pump.

Calibration process

Spirometry/Calibration

In case of several connected devices, select the one to be calibrated from the **[Device selection]** list.

The calibration should be performed in two steps. At first the peak flow should be at about 1,0 l/s and afterwards at about 5,0 l/s

Press the **[Start]** button to start calibration.

Push the fully drawn out calibrating pump with uniform speed all the way in, then pull it out all the way.

Horizontal lines on the loop curve indicate optimal flow limits. During calibration make sure the calibration curve peaks are within these lines.

The number of calibration cycles may be set as described in the Settings section (page 54). The number of recommended cycles is 10.

The first part of calibration should be done with the peak flow at about 1,0 l/s (red curves)

The second part of calibration should be done with the peak flow at about 5,0 l/s (green curves)

After the calibration process the system automatically calculates calibration factors for the different flow values.

The following values appear in the calibration result table:

- Param – name of the measured parameter
- Pred – reference value
- Meas – the measured value during calibration
- % – difference of measured value from the reference

Possible error messages

Calibration must contain at least 10 exhalations and inhalations.

Calibration was not performed properly:

- There were less calibration cycles than prescribed
- The flow meter slipped out of the calibrating pump during calibration

Asymmetry error

In this case either calibration was performed incorrectly or an error occurred in the system:

- You did not pull out or push in the calibrating pump all the way
- Check pneumatic connections
- Check flow meter assembly
- Check that the twin tube is not broken or punctured
- Check that there is no liquid in the flow sensor or the twin tube

Flowmeter error out of allowed range

If during calibration the device measures the calibration volume with greater than 20% error, there is a chance for hardware problems.

Plethysmograph calibration

P

Diffusion capacity meter calibration is performed in the

Spirometry/Calibration menu

In case of several connected devices, select **Plethysmograph** from the **[Device selection]** list.

Plethysmograph calibration has to be started with the flow meter volume calibration.

The rest of calibration has to be performed with close cabin door:

Please close the cabin door!

After closing the cabin door, you have to wait for complete thermal compensation, which is 60s. The automatic calibration process requires the following steps:

Check cabin leakage test

During leakage test both cabin time constants are checked. In this case the built-in pump inflates the cabin to 15Pa pressure, and discharge like curves indicating cabin leaking appear on the screen.

If the time constants deviate from the prescribed values, the following error message appears on the screen:

Cabin leakage out of range

In this case there is something wrong with the cabin tightness:

- Check that the cabin door is closed properly.
- Check that there is no foreign object between the cabin door and the sealing.
- Check that the cabin door sealing is intact.

Cabin pressure meter calibration

In this case the built-in sine pump creates a 15Pa pressure difference in the cabin. The change in cabin pressure is visible on the screen.

If the cabin pressure meter calibration constant falls outside the 0.5 and 2.0 range, the following error message appears:

Cabin pressure out of range

In this case there is something wrong with the cabin tightness:

- Check that the cabin door is closed properly.
- Check that there is no foreign object between the cabin door and the sealing.
- Check that the cabin door sealing is intact.

Diffusion capacity test calibration

D

Diffusion capacity meter calibration is performed in the **Spirometry/Calibration** menu

In case of several connected devices, select **Diffusion** from the **[Device selection]** list.

Before calibrating the diffusion capacity meter, you have to ensure measurement gas supply:

- Open the gas cylinder main valve.
- Check that the secondary pressure is set to 6 bar.

Flow meter volume calibration must be performed as detailed in the Flow meter calibration section (page 67.) with the following additions:

- To calibrate the gas supply system and the Demand valve an extra calibration cycle has to be performed with the calibrating pump.
- In this case the calibrating pump is harder to pull out and less flow speed is available due to the Demand valve's limited output.

Checking calibration results

It is recommended to store calibration results as the tendency over time can help draw conclusions concerning device stability and possible aging.

Click the **[Store]** button to store calibration results.

Click the **[Print]** button to print calibration results.

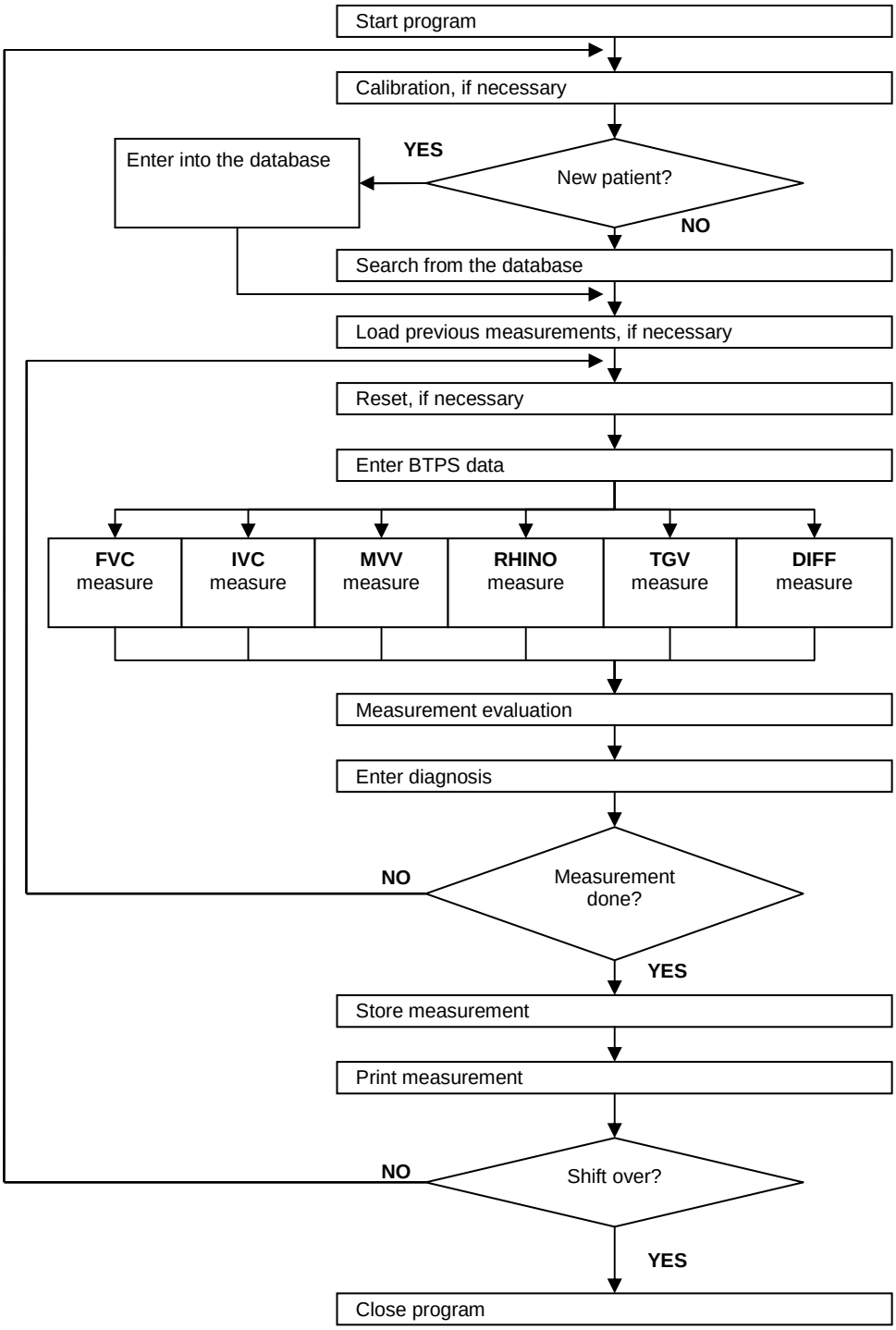
Viewing previous calibration data

Select the **[Result]** tab on the calibration window Information panel.

You can search for previous calibration results from the **[Reload calibration** data**]** time-sorted list.

MEASUREMENTS

General measurement process – daily routine



Patient selection

S R P D

Before starting the measurement it is necessary to enter patient data using one of the following methods:

- Enter new patient
- Search for patient already in the database

Preparations

S R P D

Device

Connection

Make sure that the device you wish to use is connected to the computer.

If not, connect the device as detailed in the Installation (8. page) section.

Selection

Select the device you wish to use from the **[Device selection]** list, because basic lung function tests (FVC, IVC, MVV) can be performed with any of the devices.

Patient circuit

To prevent cross contamination a new disposable bacterial and viral filter must be connected before each patient measurement.

The height of patient circuit of the Plethysmograph and Diffusion capacity test is freely adjustable according to patient comfort.

Patient

Recommended body position

- Sitting on a chair
- Straight back
- Level head
- Tight clothing or jewels must not prevent free breathing

Directions

Respiratory examination requires patient cooperation so patient preparation and instructions are important for the measurement:

- Let the patient know the measurement process and goal
- Show the patient how to take in the mouthpiece, especially in case of the bite-grip mouthpiece used with Plethysmograph and Diffusion capacity test
- Prepare the patient for any unusual and uncomfortable events, such as shutter closing or breath holding.
- In case of the Diffusion capacity meter it is possible to practice without inhaling the gas mixture.

Calibration

S R P D

Regular calibration ensures maximum accuracy.

Automatic warnings

Warning time interval can be entered for all device types. When this expires the device warns the user to perform calibration again. In this case it is recommended to perform the calibration.

Calibration is detailed in the Calibration section (Page 67).

Entering environmental data

S R

Entering exact environmental data is necessary for proper BTPS correction.

If the temperature, humidity or air pressure changes, the data must be reentered.

BTPS

The top right part of the individual measurement windows contain the BTPS data panel where you can enter the environmental data.

Automatic BTPS parameter measurement

P D

The Plethysmograph and the Diffusion capacity test has environmental data measurement unit.

These devices automatically measure the environmental data and display them in the BTPS panel.

Attention!
The Plethysmogram measures the environmental conditions inside the cabin. Data measured in a long closed, overheated cabin is not suitable for measurements with a separate device.

Zero setting

S R

For exact volume measurement the zero setting of flow meter channel must be performed immediately before the measurement.

Preparation

There cannot be any flow through the flow meter during zero setting, so the patient cannot take the connected mouthpiece into the mouth.

Notice P D

In case of Plethysmograph and the Diffusion capacity test pneumatic valves detach the flow meter from the pressure transducer, so zero setting occurs automatically in the background.

Patient may continue breathing thru the flow meter.

Zero setting process

The program automatically starts the zero setting process immediately before each measurement.

The system evaluates the data measured during the zero setting process, and displays an error message and repeats the zero setting process if a zero error is encountered.

Manual zero setting

You can reset the currently selected device anytime with the **[Zero]** button next to the **[Device selection]** list in the program header.

Notice

Zero setting is automatically performed before calibration.

Measurement

S R P D

The individual measurement operating modes are detailed in the Measurement modes section (page 82).

Measurement evaluation

S R P D

You can simultaneously perform and display max. 8 measurements.

Measurements deemed not appropriate can be deleted and a new one can be performed.

The system selects the best measurements based on different aspects for each measurement operating mode.

Sort order aspects

Forced Vital Capacity

Decreasing order based on **FVC+FEV*1.0** sum

Larger values are better

Inspiratory Vital Capacity

Decreasing order based on **IVC** value

Larger values are better

Hyperventilation

Decreasing order based on **MVV** value

Larger values are better

Rhinomanometry

Increasing order based on **RES [75]** value

Smaller values are better

TGV and Resistance

Decreasing order based on **TLC** value

Larger values are better

or

Increasing order based on **Req** value

Smaller values are better

Use the switches above the summary table to change the sort order

Diffusion capacity test

Decreasing order based on **TLC** value

Larger values are better

Pairing

R

In case of the Rhinomanometer the two nostrils' resistance measurement may differ in time, so before storing them in the database the two sides' measurements must be paired.

The Rhinomanometer's measurement screen has a separate summary table for right and left nostril measurements.

The program automatically pairs the right and left nostril measurement pairs based on quality or measurement time.

Normal mode

In case of a simple measurement it is recommended to sort the measurements based on airway resistance.

PRE/POST

In case of comparison measurement it is recommended to sort the measurements based on measurement time, so the first right side measurement is paired with the first left side measurement.

Measurement selection

Measurement management requires the selection of individual measurements:

- Click on a single point on a curve with the mouse button

or

- Click on the line in the summary table belonging to the curve.

The selected curve appears on the graph with a dotted line, the summary table's appropriate line is light blue.

Measurement selection for storage

All measurements are displayed in the measurement summary table

Colour of serial number is identical to the colour of the curve

There are two icons next to their number:

The first icon indicates the measurement's technical quality:

The measurement is technically correct.

The measurement is technically incorrect.

The second icon indicates the given measurement's status:

Visible curve

The measurement appears on the graph with a solid line.
The system can store and print the measurement.

Questionable curve

The measurement appears on the graph with a dashed line.
The system can store and print the measurement.
However, they are easily distinguishable on the graph for the user.

Turned off curve

The system does not store or print this measurement. Unlike when deleted, the curves can be displayed again at anytime.

Changing status:

- Select the measurement and the required curve will be dashed.
- Clicking on the selected line again will rotate the curve status.

Selecting the best measurement

Press the **[Best]** button to have the program automatically display the three best measurements and turn off the rest.

Press the **[All]** button to display all performed measurements.

Click the **[Report]** button to select just one from a couple of measurements. Only the selected curve will be visible all the others will be switched off.

Delete measurement

It is possible to delete measurements not already stored:

- Select the measurement and the required curve will be dashed.
- Press the **[Delete]** button.

Enter comment

S R P D

A separate comment may be entered for all measurement modes.

All comments are stored separately in the database.

- Click on the **[Diagnose]** icon to open Diagnose composer
- Select the measurement mode or the Patient mode from the list to which you would like to add a comment
- Enter the comment
- Press the **[Store]** button to store the comment in the database attached to the measurement

Previous comments

Previously created comments for the given measurement mode can be viewed anytime in the **[History]** list. The currently entered comment is not lost when viewing a previous or another measurement modes' comments. To display the comment select the measurement mode you would like to edit from the list.

Store

S R P D

To store curves marked **Visible** and **Questionable**, press the **[Store]** button.

Successful data storage returns a feedback.

Printing

S R P D

Printable data is divided into several groups:

- Complex report on lung function tests: FCV, IVC, MVV, TGV, TLCO
- Compliance
- Rhinomanometer
- Provocation test
- Audiometry

PRE/POST

The system can print two types of reports:

- Normal report: Three measurements' results simultaneously.
- PRE/POST report: Two measurements' results simultaneously and their difference in absolute and percentage format.

Customized reports

The printed report has the following parts:

- Header
- Parameter table
- Graphs
- Comment

The header is the only fixed part of the header, the other three may be turned on and off arbitrarily, only the desired parts make it into the report.

Highlight rows

To highlight odd rows at colour or grayscale printing select the **[Highlight odd rows]** checkbox

Simplified report

To print only the best measurements of all modes select the **[Just the best measure]** checkbox

Printing

Before printing measurement results have to be stored so the printed reports can be followed up.

- Click the **[Print…]** icon in the main menu
- Select the graphs, tables and manual diagnosis you would like to print
- Select the report language
- Select the report type: normal or PRE/POST
- Click on a button in the **[Print** preview**]** section to view the print preview
- After making the necessary settings, click the **[Print]** button

During printing graph display is similar to on-screen display:

- Complete curve or only the representative curve section
- One or more graphs

Export report into the graphical formats

S R P D

This feature provides export of the printed report into the commonly used graphical formats. Exported reports can be stored and for example sent as an attachment to an e-mail.

Supported formats

- PDF, Adobe Acrobat document
- GIF picture
- JPEG picture
- BMP Windows Bitmap picture
- EMF and WMF vector graphics

Settings

The Export function is in the Report edition window

- Click on the **[Print…]** button at the main menu

Contents and the format of the exported report are fully identical to the printed version. More information can be found in the chapter Printing on the 78. page.

Export procedure

Prior to printing and exporting results of measurements have to be stored in order to provide reliable traceability

- Click on the **[Print…]** button at the main menu
- Select graphs, tables and text fields to be exported
- Select the language of the report
- Select the type of the report PRE/POST

- For previewing the report click on any button at the **[Print preview]** section
- After setting click on the **[Store]** button

Exported graphs are fully identical to the graphs shown on the screen:

- Full curve or only the important part
- One or more graphs

Interface to information systems

Interface to frame systems

Our system provides communication according to the more commonly used protocols:

- Health Level Seven (HL7)
- Geräte Daten Träger (GDT)

These protocols provide exchange of the patient data and measured results between the lung diagnostics equipment and the frame systems. These protocols are predefined by the System administrator consequently can not be modified by the user.

Receiving the request for tests

Click on the [LINK…] button in the main menu and open the Import/Export window

According to your frame system type click one of the **[HL7]** or **[GDT]** buttons in the Import section in order to receive a Request for tests

If a Request for test is available the system automatically acquires it and lists all the requested tests

Exporting

Click on the [LINK…] button in the main menu and open the Import/Export window

According to your frame system type click one of the **[HL7]** or **[GDT]** buttons in the Export section. The system automatically exports the results of the tests.

Filling special forms

The system provides filling customer defined forms. Templates of the forms can be compiled in any ASCII format (HTML, XML, CSV etc.). Compilation of the form is the competence of the System administrator.

Filling a form

User may select a form from the preinstalled templates.

Click on the **[LINK…]** button in the main menu to open the Import/Export window

Click on the **[HTML]** button to open the Custom Report window

Select the desired template from the a **[Templates]** list

Click on the **[Select]** button and the form is automatically filled out

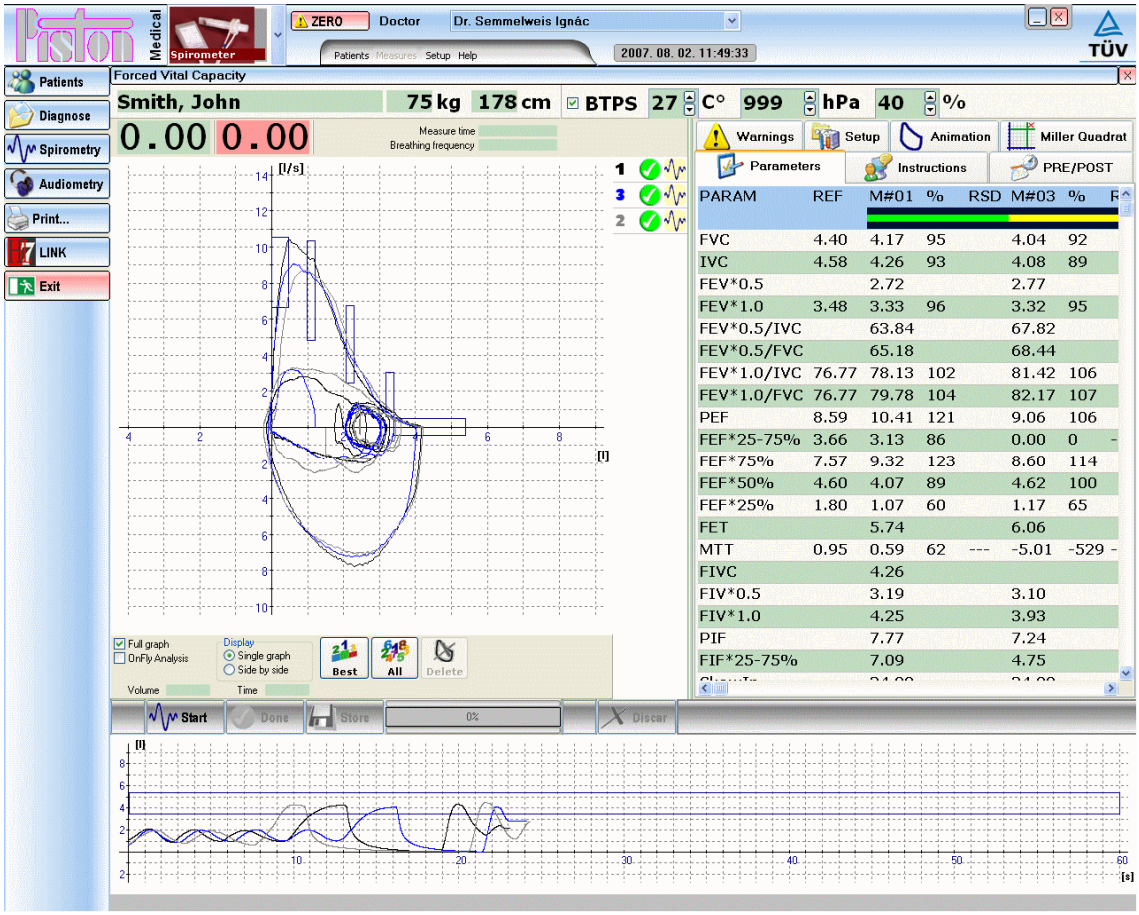
MEASUREMENT MODES

Forced Vital Capacity

S R P D

Measurement goal

The goal of the measurement is to get parameters of the volume forced expiration and inspiration



Measurement process

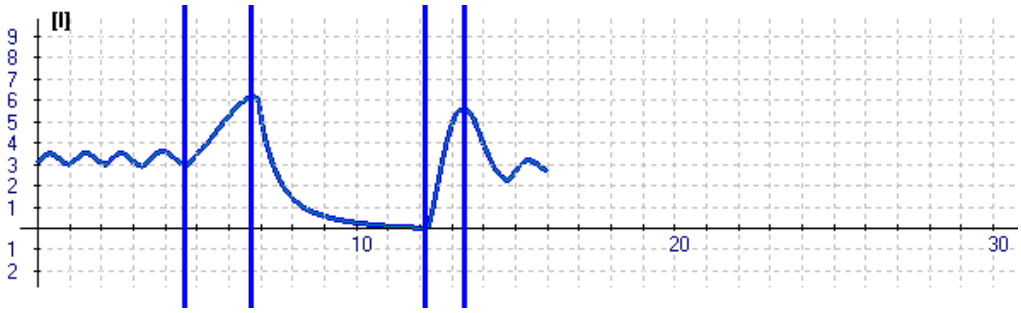
Instruct the patient to perform the following manoeuvres:

- Put on the nasal clip so he / she can only breath through the nose.
- Take at least three quiet breathings
- Take as deep as possible inspiration
- Take as fast and deep as possible expiration
- Take as fast and deep as possible inspiration

The patient has 60 second to perform the FVC manoeuvre

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct FVC manoeuvre
Phases: quiet breathing, deep inspiration, forced exhalation, forced inhalation, return to normal breathing.

Miller Quadrant

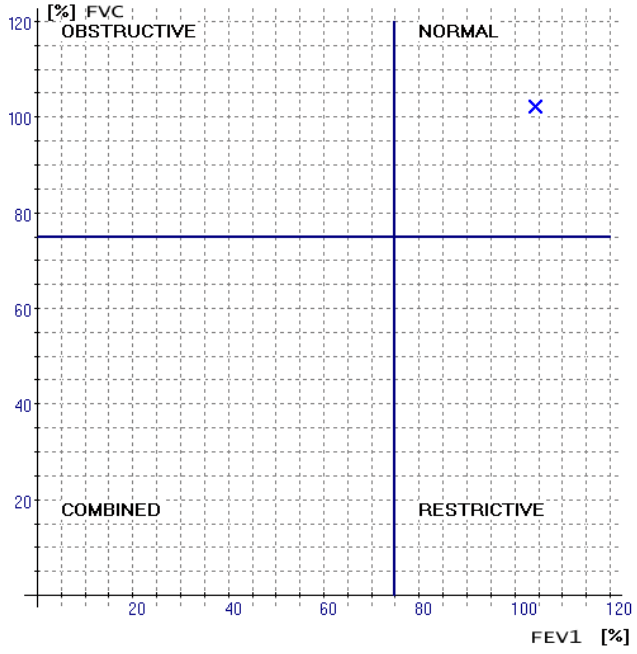
The Miller Quadrant an effective graphical tool which helps making the lung function diagnoses.

The vertical axle shows the ratio of FVC reference value and the measured value

The horizontal axle shows the ratio of FEV*1,0 reference value and the measured value

The diagram is divided into four quadrants:

- Normal
- Restrictive
- Obstructive
- Combined



Animation

Animation with blowing away dandelions helps with motivating children to reach their maximum effort during FVC manoeuvre

Inspiratory Vital Capacity

S R P D

Measurement goal

The goal of the measurement is to get the parameters of the maximal inspiration.

Measurement process

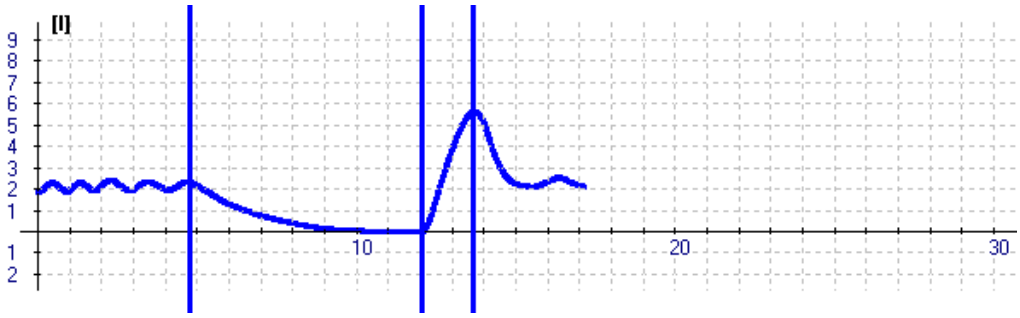
Instruct the patient to perform the following manoeuvres:

- Put on the nasal clip so he / she can only breath through the nose
- At least three quiet breaths
- As deep expiration as possible
- As deep inspiration as possible
- Optionally as deep expiration as possible to get the SVC (Slow Vital Capacity) parameter

The patient has 60 second to perform the IVC manoeuvre

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct ICV manoeuvre

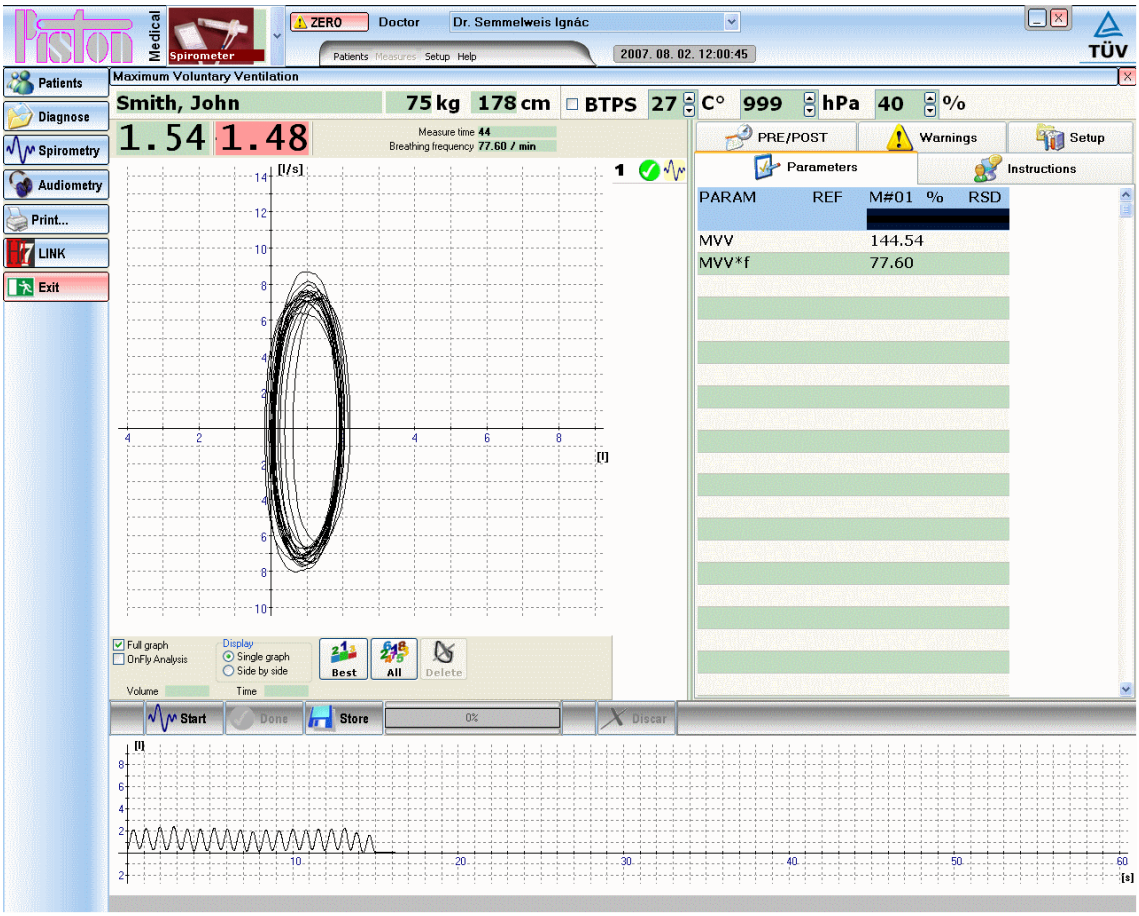
Phases: Quiet breathing, complete deep expiration, complete deep inspiration, return to normal breathing.

Maximal voluntary ventilation

S R P D

Measurement goal

The goal of the measurement is to get the amount of volume the patient can move in a given time.



Measurement process

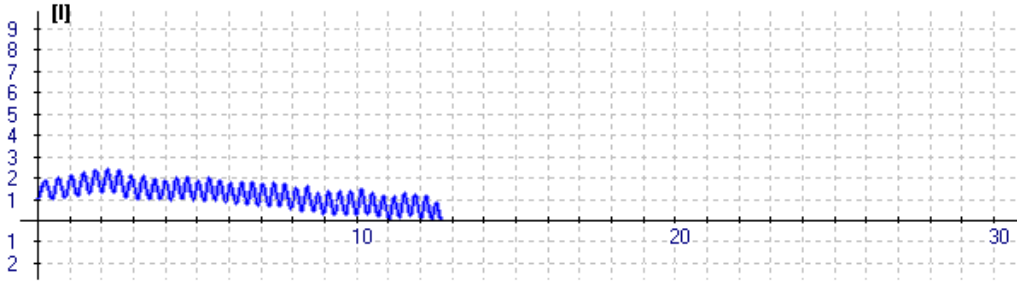
Instruct the patient to perform the following manoeuvres:

- Put on the nasal clip so he / she can only breath through the nose.
- Move as much air as possible.
- The patient can choose the breath frequency as convenient
- To prevent hypocapnia it is not recommended to continue this measurement for more than 15 seconds.

The patient has 60 seconds to perform MVV manoeuvre.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



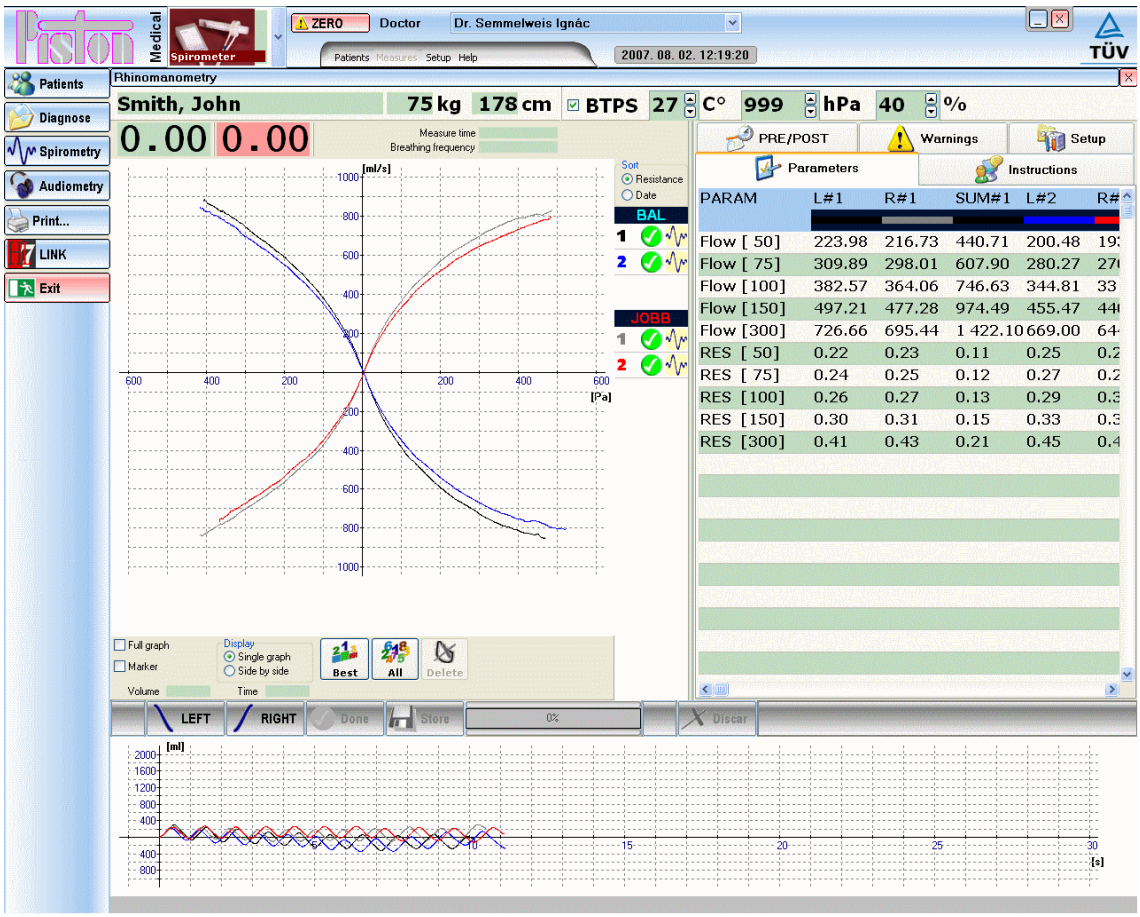
Correct MVV measurement
The patient breaths quickly, evenly during the measurement.

Rhinomanometry

R P

Measurement goal

The goal of the measurement is to get the patient's nasal airway resistance.



Measurement process

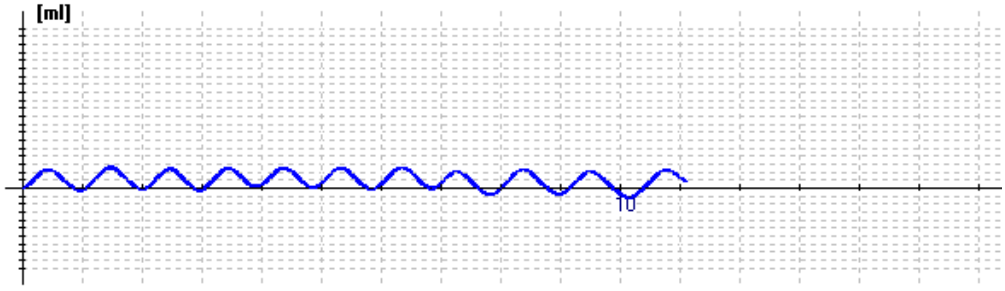
The following series of manoeuvres must be performed:

- The patient must clean the nasal canals
- Place the appropriate size nasal plug into the side opposite the measured one
  So if you would like to measure the resistance of the right nasal canal, place the nasal plug into the left nostril, and vice versa
- Have the patient hold the appropriate size facial mask against his / her face to prevent leaking
- The patient can only breathe through the free nostril, not through the mouth

The patient has 60 second to perform the manoeuvres, but usually a few even respiratory cycles are enough.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct Rhinomanometry measurement
The patient breathes relaxed during the measurement.

Selecting the loop curve

The system records several respiratory cycles during the measurement and by default displays their average.
However, you have the option to view the curves one-by-one:

- Select the measurement you would like to modify from the measurement summary table
- Click with the mouse on the spirogram – the marker jumps to the next cycle
- The system automatically recalculates the parameters

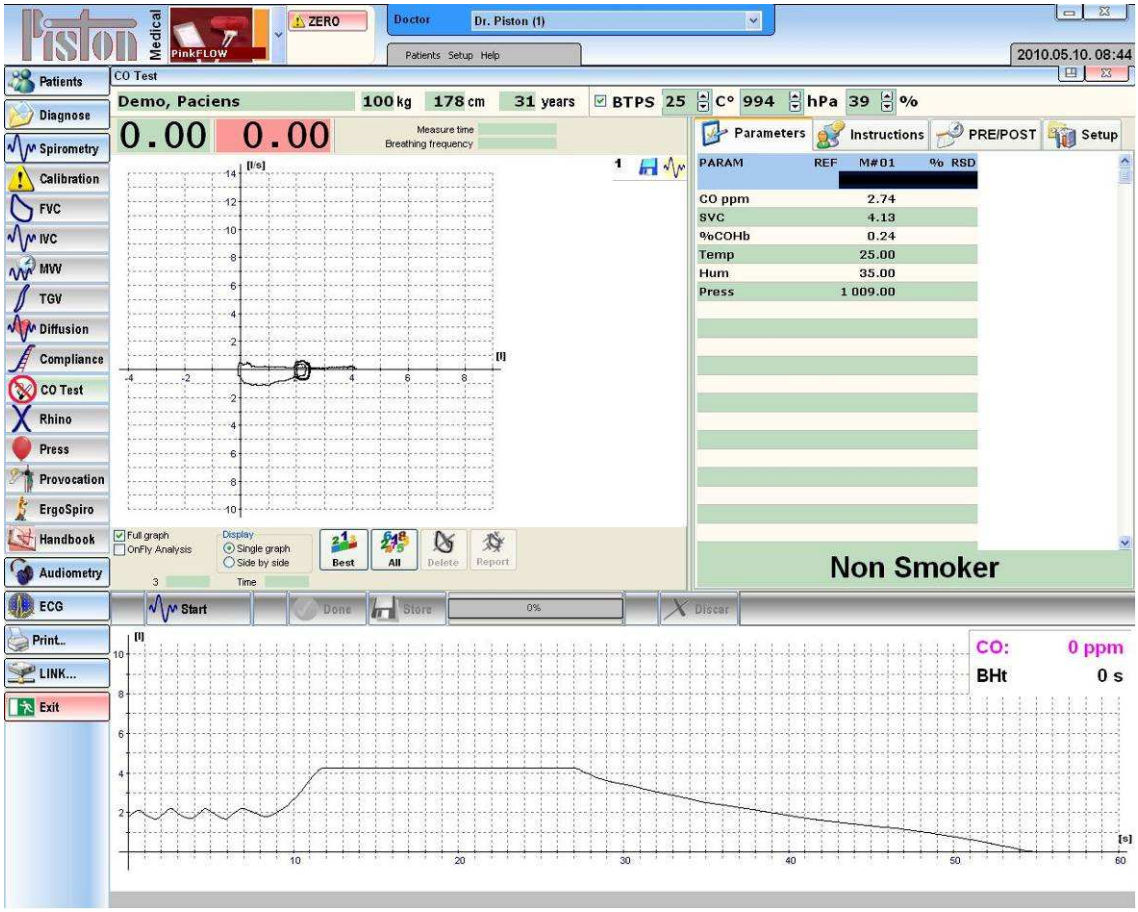
Breath carbon monoxide monitoring

P D

Measurement goal

The goal of the measurement to follow up the smoking habits of the patient and assist the smoking cessation program.

Attention
Avoid measuring patients whose exhalation may content alcohol because the CO sensor of the device may get wrong



Measurement process

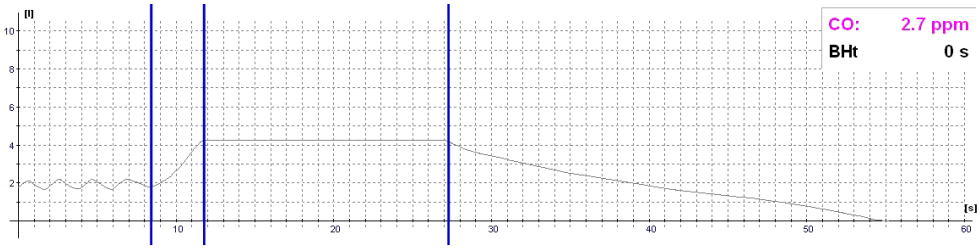
The following series of manoeuvres must be performed:

- Place the Nasal clip to avoid the breathing thru the nostrils
- Perform at least 3 quiet breathings
- Breath hold et least for 10 seconds
- Slow and even full expiration

The patient has 60 second to perform the manoeuvres.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.



Correct Breath CO measurement
Phases: Quiet breathing, complete deep inspiration, breath holding, complete slow expiration

Evaluation of the results

The following evaluations are given by the system after the measurement:

- Non Smoker
- High value for non-smoker
- Smoker
- Frequent smoker
- Addicted smoker
- Heavily addicted smoker
- Dangerously addicted smoker

Thoracic Gas Volume

P

Measurement goal

The goal of the measurement is to get the mechanical parameters of the patient's respiratory system:

- Thoracic gas volume
- Total lung capacity
- Airway resistance and its components

Premises

To get the IVC parameter value required to determine Thoracic Gas Volume measurement parameters:

- Perform an IVC measurement before the TGV measurement. The advantage to this is that the TGV manoeuvre becomes simpler.
- Retrieve an IVC measurement from the database that looks recent.
- The IVC measurement can be performed even during the TGV measurement, after shutter opening. The advantage to this is that you get all the parameters in one

measurement; the disadvantage is that the measurement is more complicated

The system always selects the most recent IVC measurement result.

Preparation

TGV is a complex measurement, requiring considerable cooperation from the patient:

- Seat the patient in the cabin
- Set the chair height
- Set the height of the patient circuit
- Place the nasal clip so the patient can only breath through the mouth
- Explain the exact measurement process to the patient
- Prepare the patient for unexpected and unusual events, such as shutter closing
- Close the cabin door
- Set the speaker volume

Measurement process

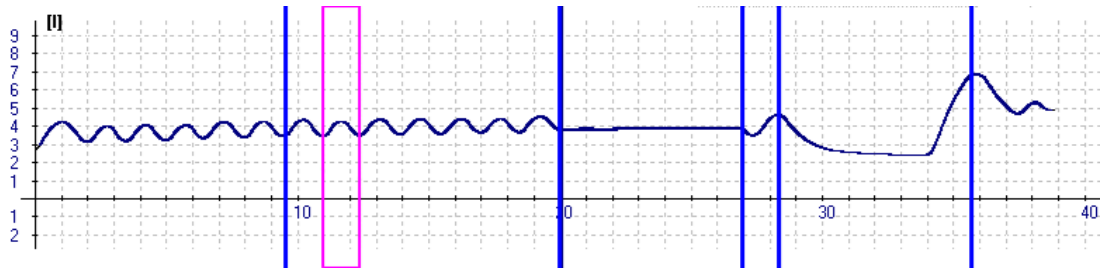
The following series of maneuvers must be performed:

- The metronome turns on after the measurement starts.
- The countdown to thermal compensation begins.
- The patient can practice breathing to the metronome during the waiting period, the current respiratory frequency is continuously displayed in the top part of the measurement window.
- After the waiting period tell the patient to evenly breath according to the metronome. The current respiratory frequency is continuously displayed in the top part of the measurement window, in the **[Breathing** frequency**]** field. In case of respiratory frequency that is extremely different from the settings, the field changes to red.
- When the patient is breathing evenly according to the metronome, press the **[Start]** button to start Resistance, then TGV loop recording.
- During shutter closing have the patient try to perform even expiration and inspiration manoeuvres. The patient does not have to exert too much force, but has to suck on it and has to push against the shutter.
- After shutter opening let the patient rest, then optionally instruct him / her to perform a complete IVC manoeuvre – a complete expiration followed by a complete inspiration.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.

Marker



Correct TGV measurement

Phases: quiet breathing, quiet breathing during Resistance loop recording, shutter closing during TGV loop recording,
complete IVC manoeuvre, return to normal breathing.

Selecting resistance loop

Several (5 by default) Resistance loops are recorded during the measurement. From these the system automatically selects the loop closest to the average.

If you would like to select the Resistance loop into the report manually, follow these steps:

- Select the measurement to be modified in the measurement summary table.
- Click with the mouse on the spirogram – the marker jumps to the next cycle.
- The system automatically recalculates the parameters.

Diffusion capacity test

The system provides two alternative methods for measuring diffusion capacity:

- Single-Breath – Breath holding method

The Breath holding method is the standard way for diffusion capacity measurement. The patient has to make a deep inspiration from the gas mixture and has to hold the breath for a certain period of time and afterwards has to exhale slowly and evenly

- Intra-Breath – Without breath holding method

An alternative method for diffusion capacity measurement for the poorly cooperating patients who are unable for the breath holding manoeuvre

It is enough for the patient to make a deep inspiration from the gas mixture and afterwards the patient may start the slow and even expiration immediately

After changing the gas cylinder enter the actual gas concentrations according to Certificate issued by the Filling station as described in the Installation (page 8) section

Single-Breath Diffusion capacity test

D

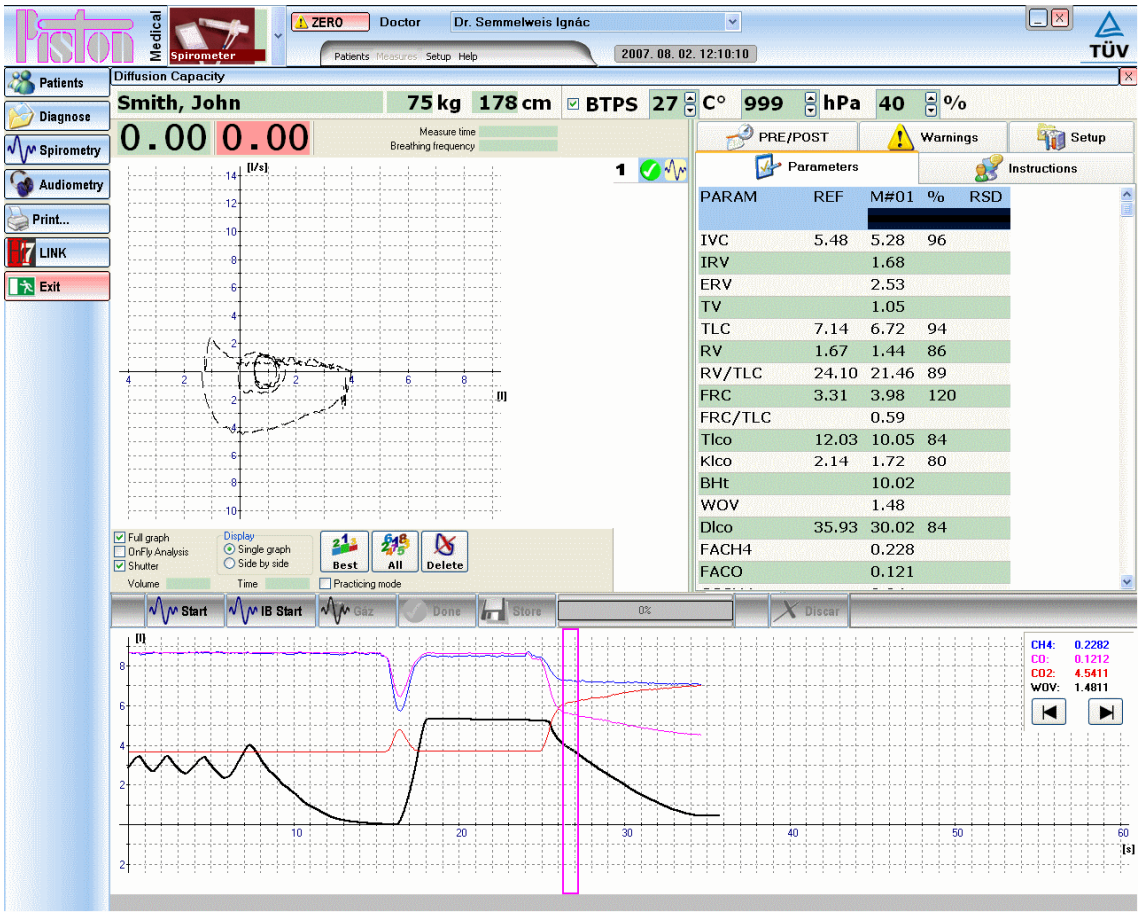
The Single-Breath method is the standard way for diffusion capacity test

Measurement goal

The primary goal of the measurement is to get the oxygen binding capacity of the patient's lung:

- Transfer factor calculated for carbon monoxide
- Functional residual capacity
- Total lung capacity
- Residual lung capacity

IMPORTANT!
There must be at least 5 minutes between measurements so the measurement gas mixture can completely clear out from the patient's lung.



Preparation

Diffusion capacity measurement is a complex process, requiring considerable cooperation from the patient:

- Seat the patient.
- Set chair height.
- Set measurement head height.
- Place the nasal clip so the patient can only breath through the mouth.
- Tell the patient the exact measurement process.
- Prepare the patient for unexpected and unusual events, such as gas mixture inhalation through the Demand valve, and holding the breath.

Measurement process

The following series of manoeuvres must be performed:

- The patient must breath evenly after the measurement started.
- The **[Gas]** button is enabled after the third relaxed breath.
- Instruct the patient to exhale relaxed, deep, completely.
- Press the **[Gas]** button when the patient started the complete deep exhalation.
- During the next inhalation the patient inhales the measurement gas mixture and must be instructed to inhale completely, deeply.
- Breath holding begins after inhalation, the remaining time appears on the screen.
- Warn the patient to hold the breath, do not press it onto the shutter and do not try to inhale.
- The metronome indicates the end of breath holding with a visible and audible signal.
- When the shutter opens, instruct the patient to exhale relaxed; the patient cannot inhale until gas sampling is performed.
- The metronome indicates the end of gas sampling with a visible and audible signal.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.

Practice operating mode

Turning on the **[Practicing mode]** option lets the patient practice the complete measurement process without inhaling the measurement gas mixture.

Use the practice operating mode for a few measurements with a badly cooperating patient.

Using the shutter

You can select whether the shutter is closed or opened during breath holding:

If the shutter is closed, the patient must make sure that he / she holds the breath and does not press it onto the shutter, because this increases the alveolar pressure and change the level of diffusion.

If the shutter is open, the patient must make sure not to inhale or exhale during breath holding, because this changes the gas concentration in the patient's lung and effects measurement accuracy.

Measurement instructions

During measurement the system continuously indicates the upcoming manoeuvre.

It is important to note that the system does not indicate the immediately performed task, but the next in line.

For example "Complete, deep inhalation" appears towards the end of the complete deep exhalation, however it is obvious that inhalation comes after the completely finished exhalation and not immediately.

Possible error messages during closed-shutter breath holding

Mouth pressure out of allowed range during breath hold time. Repeat the measurement if possible!

Due to the mouth pressure variation the measured Tlco, Dlco and Klco values can be used only for orientation.

Valsalva- or Miller effect.
The patient must take care to hold his / her breath and not press it onto the shutter and not try to inhale.
This can increase or decrease the alveoral pressure, and change the diffusion amount.

Possible error messages during open-shutter breath holding

Expiration during inspiration of gas mixture. Repeat the measurement if possible!

If the shutter is open, the patient must take care not to inhale or exhale during breath holding.
This can change the gas concentration in the lung and effect measurement accuracy.

The patient did not breath in, the measured RV value is correct, but Tlco, Dlco and Klco values are invalid.

Since methane quickly mixes into the lung, the breath holding time has less effect on the RV and TLC measurement result. However, carbon monoxide diffusion greatly depends on breath holding time, so transfer factor calculation is not possible.

Patient made breathing during the breath hold time, the measured RV, TLC, Tlco, Dlco and Klco values are invalid.

As a result of inspiration the gas mixture in the lung is diluted to an unknown degree, so measurement evaluation is not possible, and the measurement must be repeated!

Possible error messages during and after gas sampling

Inspiration during expiring gas mixture

The patient breathed back during gas sampling, so the results are inaccurate, the measurement must be repeated.

Too short expiration time

The patient did not exhale long enough for reliable gas sampling.

If the gas concentration curves and the measured values appear correct, you can keep the measurement.

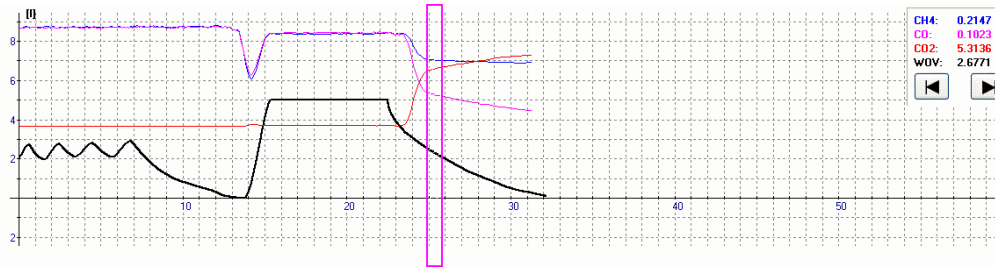
Measurement refinement

The system automatically optimizes the gas sampling position, but manual refining may be needed:

- Select the measurement to be refined in the measurement summary table
- The gas sampling marker appears on the spirogram
- Use the arrows on the gas concentration panel to move the marker left and right.
- Use the methane (CH_4) curve (blue graph) to find the optimal marker position, where the curve is almost horizontal, but is close enough to the curve inflexion point
- When manually setting the marker you have to be careful, because it significantly affects the measurement results.

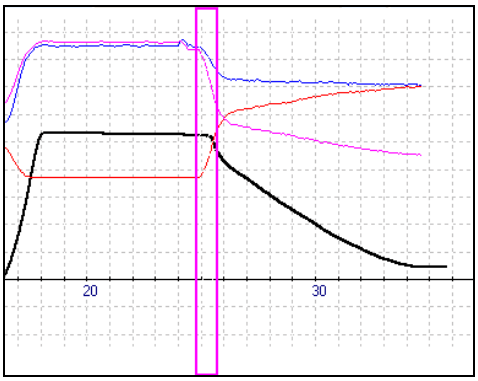
Marker

Gas concentration panel

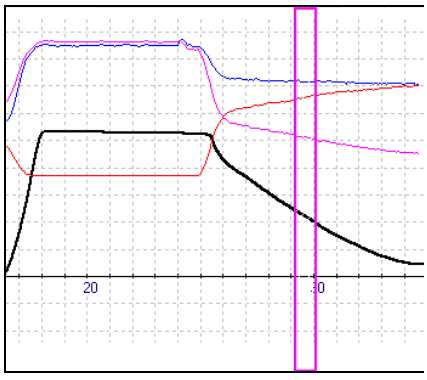


Correct Diffusion capacity measurement
Phases: quiet breathing, complete deep expiration, even gas mixture inspiration, breath holding, even expiration during gas sampling

Incorrect marker positions



The marker is **too much to the left**, at the beginning of the expiration curve



The marker is **too much to the right**, at the end of the expiration curve

Intra-Breath Diffusion capacity test

D

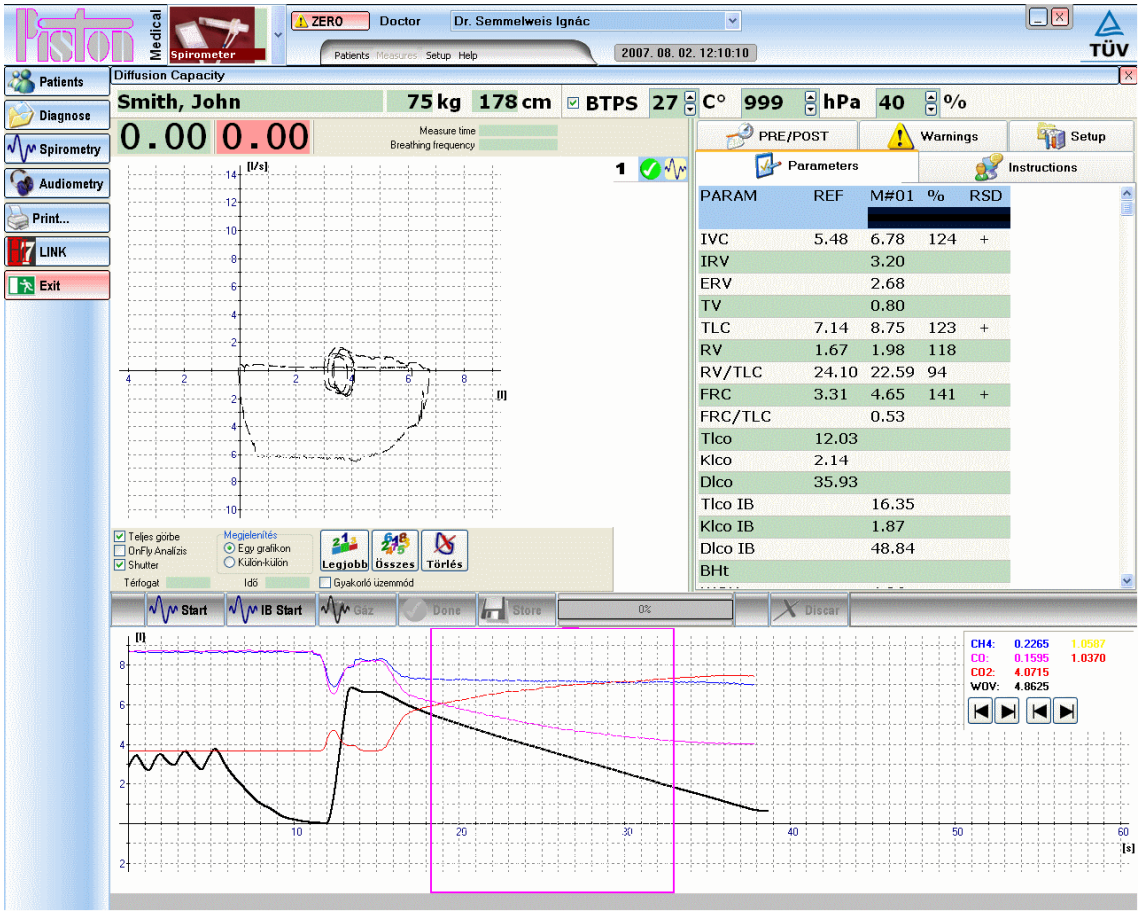
An alternative method for diffusion capacity measurement for the poorly cooperating patients who are unable for the breath holding manoeuvre

Measurement goal

The primary goal of the measurement is to get the oxygen binding capacity of the patient's lung:

- Transfer factor calculated for carbon monoxide
- Functional residual capacity
- Total lung capacity
- Residual lung capacity

IMPORTANT!
There must be at least 5 minutes between measurements so the measurement gas mixture can completely clear out from the patient's lung.



Preparation

Diffusion capacity measurement is a complex process, requiring considerable cooperation from the patient:

- Seat the patient.
- Set chair height.
- Set measurement head height.
- Place the nasal clip so the patient can only breathe through the mouth.
- Tell the patient the exact measurement process.
- Prepare the patient for unexpected and unusual events, such as gas mixture inhalation through the Demand valve, and holding the breath.

Measurement process

The following series of manoeuvres must be performed:

- The patient must breathe evenly after the measurement started.
- The **[Gas]** button is enabled after the third relaxed breath.
- Instruct the patient to exhale relaxed, deep, completely.
- Press the **[Gas]** button when the patient started the complete deep exhalation.
- During the next inhalation the patient inhales the measurement gas mixture and must be instructed to inhale completely, deeply.
- When the shutter opens instruct the patient to exhale slowly and evenly at approximately 0,5 litre/sec flow rate
- The metronome indicates the end of gas sampling with a visible and audible signal.

Push the **[Done]** button to stop the measurement.

Push the **[Discard]** button to delete the measurement.

Practice operating mode

Turning on the **[Practicing mode]** option lets the patient practice the complete measurement process without inhaling the measurement gas mixture.

Use the practice operating mode for a few measurements with a badly cooperating patient.

Using the shutter

If the patient circuit is equipped with the optional exhalation orifice and you are going to use it select the Shutter option.

If the patient circuit has no exhalation orifice or you are not going to use it unselect the Shutter option.

Measurement instructions

During measurement the system continuously indicates the upcoming manoeuvre.

It is important to note that the system does not indicate the immediately performed task, but the next in line.

For example “Complete, deep inhalation” appears towards the end of the complete deep exhalation, however it is obvious that inhalation comes after the completely finished exhalation and not immediately.

Possible error messages during and after gas sampling

Too short expiration time

The patient did not exhale long enough for reliable gas sampling.

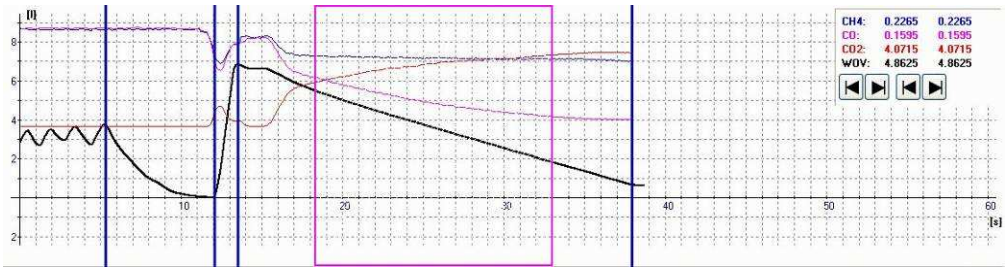
If the gas concentration curves and the measured values appear correct, you can keep the measurement.

Measurement refinement

The system automatically optimizes the gas sampling position, but manual refining may be needed:

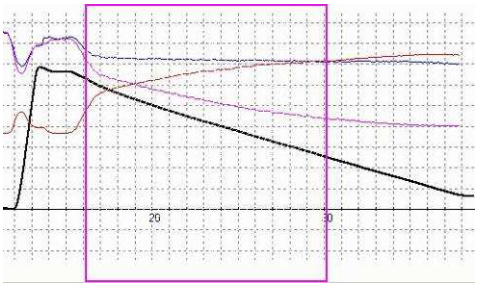
- Select the measurement to be refined in the measurement summary table
- The gas sampling marker appears on the spirogram
- Use the arrows on the gas concentration panel to move the marker left and right.
- Use the carbon monoxide (CO) curve (purple graph) to find the optimal marker position where part of the curve inside of the markers almost straight but it is close enough to the curve inflexion point
- When manually setting the marker you have to be careful, because it significantly affects the measurement results.

Marker **Gas concentration panel**

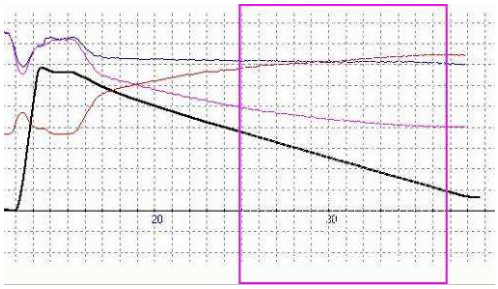


Correct Diffusion capacity measurement
Phases: quiet breathing, complete deep expiration, even gas mixture inspiration, slow and even expiration during gas sampling

Incorrect marker positions



The marker is **too much to the left**, at the beginning of the expiration curve



The marker is **too much to the right**, and the CO curve is not straight yet

Compliance

P D

Measurement goal

The primary goal of the measurement is to get the compliance of the lungs or with other words to determine the change of the lungs volume as a function of the pressure against the wall of the lungs.

There is a possibility to measure the Dynamic and Static Compliance sequentially during one manoeuvre.

To get the value of the Transpulmonary pressure we have to measure the pressure of the intrapleural cavity with the help of oesophageal balloon:

$P_{TP}=P_{AV}-P_{PL}$ where P_{TP} - Transpulmonary pressure

P_{AV} - Alveolar pressure

P_{PL} - Pleural pressure (oesophageal pressure)

Oesophageal balloon

We propose the following oesophageal balloon for the Compliance meaurement:

Manufacturer: Cooper Surgical

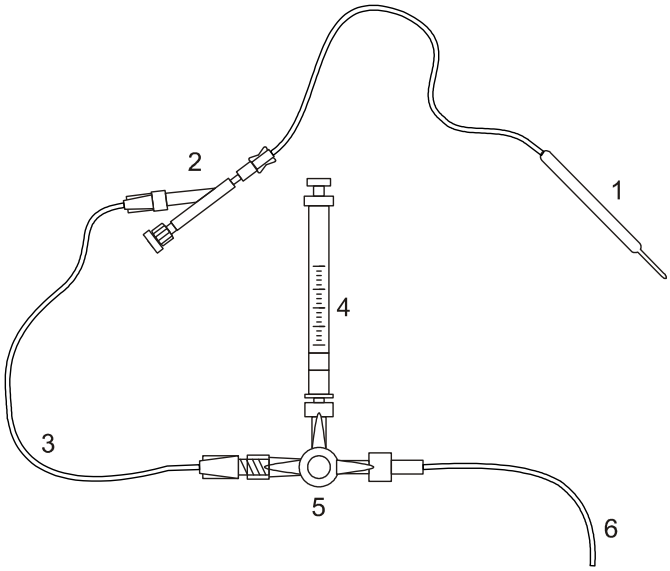
Trumbull, CT06611, USA

Tel: +1-203-601-5200

Decricption: Esophageal Balloon Catheter Set

Type: 47-9005

Of course any other type of oesophageal balloon can be used but the current description is relevant only for the specified type.



Parts of the Esophageal Balloon Catheter Set:

1. Esophageal Balloon Catheter
2. Stylet Y connector
3. Extension tube
4. Syringe, Glass 5 cc
   (The set does not contain it)
5. Three way Stopcock
6. Pressure transducer tubing

Preparation

1. Have available for use a nemesis basin, tissues, a protective drape, topical anaesthetic, water –soluble lubricant and a 1 to 5 cc glass syringe, a glass of water and a straw
2. Select a naris with the best airflow for catheter insertion
3. If necessary apply a suitable topical anaesthetic (e.g. 2-4% Lidocaine Spray) to the patient's nasal passage and throat
4. Remove the sterile radiopaque catheter with the stylet from its protective sleeve from the catheter and discard
5. Remove the yellow protective sleeve from the catheter (1) and discard
6. Apply water-soluble lubricant to the distal tip of the catheter (1)
7. With the patient's head in a neutral position or flexed slightly forward, slowly insert the catheter (1) through the naris and hypo pharynx using a gentle advancing motion. The insertion may be easier if the patient is sipping water thru the straw.
8. Avoid placement of the catheter (1) in the trachea. Tracheal placement can be identified by patient choking or airway obstruction causing an increase in airway resistance and pressure.
9. To estimate depth in which to place catheter calculate the product of the patient's height x 0.288.
   For example the patient is 175 cm height the principal depth is 50 cm.

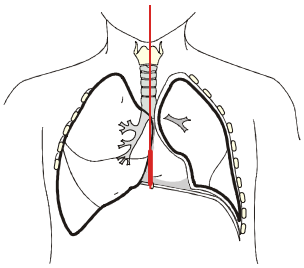
10. Advance the catheter (1) to the calculated depth mark. (If the catheter meets obstruction, DO NOT FORCE THE CATHETER. Remove it and insert it through the other naris). At this depth, the balloon will be entering the thoracic cavity.
11. Attach the extension tubing (3) to the „Y" connector of the stylet (2), a syringe (4) and an isolated physiologic transducer to the 3-way stopcock (5)

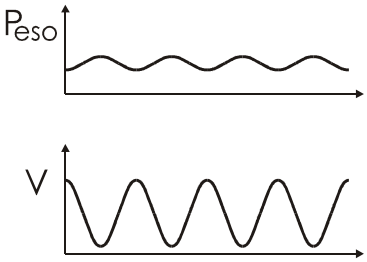
Catheter Placement

12. Turn the 3-way stopcock (5) open to the syringe (4) and extension tube (3). Evacuate all the air from the balloon (1) by pulling back on the syringe plunger (4) and then allowing the plunger to return to a nonvacuum position. Use of a glass syringe avoids creating a vacuum in the balloon catheter.
13. Turn the 3-way stopcock (5) off to the extension tube (3), remove the syringe (4) and fill the syringe (4) with 1 cc of air.
14. Attach the syringe (4) to the 3-way stopcock (5) , open the 3-way stopcock (5) from the syringe (4) to the extension tube (3). Introduce 1 cc of air into the balloon (1). The balloon (1) will now be semi inflated. An incorrect amount of air in the balloon will adversely affect pressure wave performance (see Trouble Shooting Guide below).
15. After 1 ml of air is injected, turn the stopcock (5) off to the syringe (4), and open from the extension tube (3) to the transducer to read pressure from the catheter.
    If no or a damped pressure signal is seen, the catheter (1) may need to be advanced further into the thoracic cavity or may be kinked on itself and needs to be withdrawn.
    In the absence of diaphragmatic paralysis, the pressure recorded should be negative on inspiration. A positive inspiratory pressure recording may indicate gastric placement and the catheter (1) should be pulled back.
    Pressures taken through the „Y" connector (2) are for balloon placement only. The stylet, luer cap and „Y" connector (2) are bonded into a single unit and must be removed from the catheter before taking pressure measurements for clinical purposes.
16. Once the catheter (1) has been positioned properly, disconnect the extension tube (3) from the stylet „Y" connector (2) and remove the stylet assembly from the catheter. Excessive curvature of the catheter may cause the stylet to bind in the catheter making removal difficult. If the stylet binds in the catheter during removal, instruct the patient to raise their head to straighten the catheter.

Pressure Data Acquisition

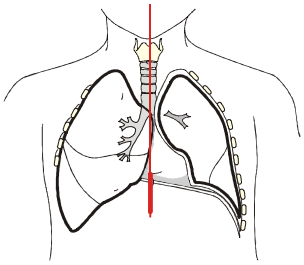
17. After removing the stylet assembly (2), reattach the extension tube (3) to the luer of the catheter (1) and repeat steps 12 through 15.
18. Radiographic placement of the balloon 81) is recommended to verify proper balloon placement.
19. When the catheter (1) is properly positioned it can be secured with tape to prevent extubation or movement.
20. Take pressure measurement.
21. Upon completion of the pressure measurements, deflate the catheter (1) prior to removal.

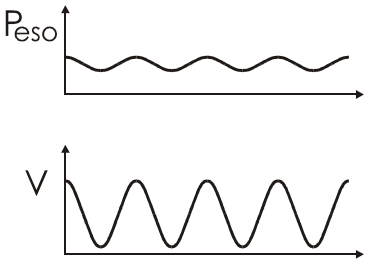




Correct position

The oesophageal pressure is in counter phase with the spirogram
It decreases during inspiration





Incorrect position

The oesophageal pressure in the same phase with the spirogram,
It increases during inspiration

The balloon is inserted too deep into the stomach
It has to be pulled up

Premises

For determination some parameters of the Compliance measurement there is a need to have the TLC and/or TGV and/or FRC measured previously. The system provides a couple opportunities for that:

- Prior to Compliance measurement make a TGV measurement
- Prior to Compliance measurement make a diffusion capacity test
- Retrieve from the database a TGV or diffusion capacity test result as an Actual measurement

If there are more TLC values the system always selects the largest one.

Preparation

Compliance measurement is a complex process, requiring considerable cooperation from the patient:

- Inform patient on the process of the measurement
- Prepare patient for the unexpected and unusual events like closing of the shutter during Static Compliance measurement
- Pushing the [Monitor] button it is possible to monitor continuously the breathing of the patient. The spirogram and the pressure of oesophageal balloon are displayed simultaneously.
- As it is described before insert the oesophageal balloon into the proper depth.

The pressure of the oesophageal balloon displayed over the spirogram with a light blue line.

The pressure of the oesophageal balloon is displayed during the preparation and the measurement furthermore during browsing when a given measurement is selected.

Measurement process

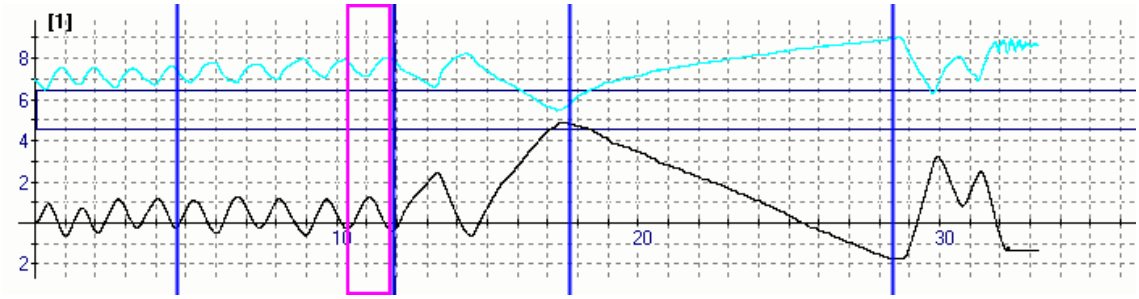
The following series of manoeuvres must be performed:

- Starting the [**Monitor**] mode the metronome starts as well
- Patient may practice breathing according to the metronome in [**Monitor**] mode. The actual breathing frequency is displayed in the middle of the upper part of the screen.
- When the oesophageal balloon is at the proper position the oesophageal pressure is in counter phase with the spirogram
- When the patient is breathing quietly and evenly push the [**Cdyn**] button to start the measurement
- After three quiet breathing cycles the Dynamic Compliance loops are recorded
- Pushing the [**Cstat**] button the Dynamic Compliance mode is finished and the a [**Shutter**] button becomes active
- Instruct the patient for the full deep inspiration and afterwards for a quiet, even and very slow exhalation (200-500 ml/sec)
- Push the [**Shutter**] button as the patient starts the full deep inspiration
- The Static Compliance measurement starts automatically as the patient starts expiration.
  During the expiration the Shutter closes automatically after certain exhaled volumes and interrupts expiration. When the Shutter is closed the Mouth pressure is recorded.
- The Static Compliance manoeuvre can be finished reaching the FRC level or it is finished automatically when the expiration flow less than 10 ml/s
- Bad dynamic or static maneuvers can be repeated within the 1 minute period but parameters will always be calculated form the last dynamic or static maneuver
- The system provides possibility for recording 8 consecutive Dynamic and Static Compliance measurement pairs

Pushing the **[Done]** button the measurement can be finished.

Pushing the **[Discard]** button the measurement can be deleted.

Marker



Correct Compliance measurement

Phases: Quiet breathing, Quiet breathing during recording of Dynamic Compliance loops, Preparation for Static Compliance with deep inspiration, Static Compliance measurement during slow and even expiration, Returning to the relaxed breathing

Selection of Dynamic Compliance loop

During the Dynamic Compliance measurement more loops are recorded.

The system selects automatically the loop which is closest to the average of the all loops.

However there is a possibility to select the desired loop manually as well:

- Select the measurement to be refined in the measurement summary table
- Click on the spirogram and marker jumps to the next cycle
- All parameters will be recalculated automatically

Manual correction

The system calculates automatically the steepness of the Dynamic and Static Compliance loops.

However there is a possibility to modify the steepness manually as well:

- Select the measurement to be corrected
- The steepness of Dynamic and Static Compliance loops can be corrected separately in the [Setup] panel at the a [Correction] filed
- All parameters will be recalculated automatically

Selection of TLC or TLC% display mode

There are two possibilities for interpretation of Compliance loops which can be selected at [Setup] panel in [Scale] section:

- Litre – The gradation of vertical axle is in absolute volume
- TLC % – The gradation of vertical axle is in percentage of TLC value

Warning! If there is no available TLC or RV value it is impossible to display the Compliance loops in TLC% mode

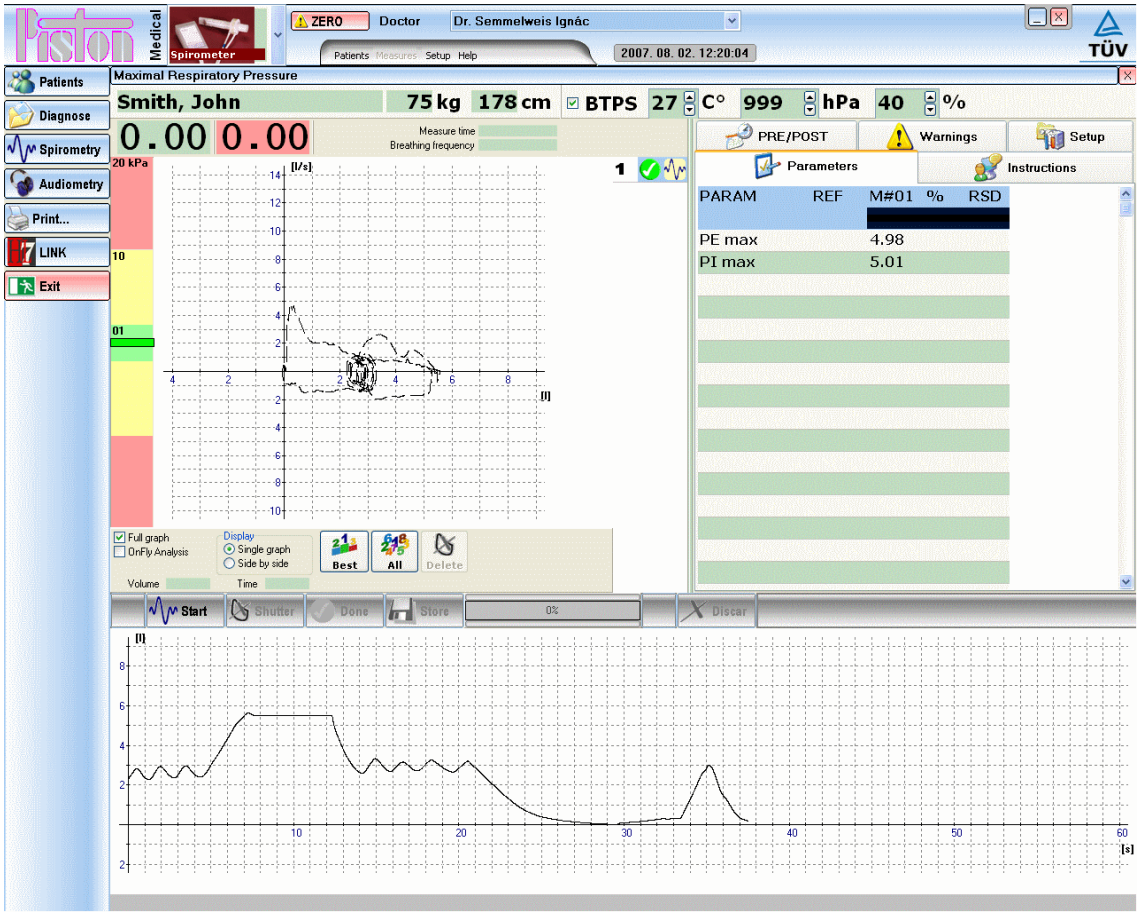
Maximum inspiratory and expiratory pressure

P D

Measurement goal

The goal of the measurement is to measure the respiratory muscle strength:

- Maximum inspiration pressure
- Maximum expiration pressure



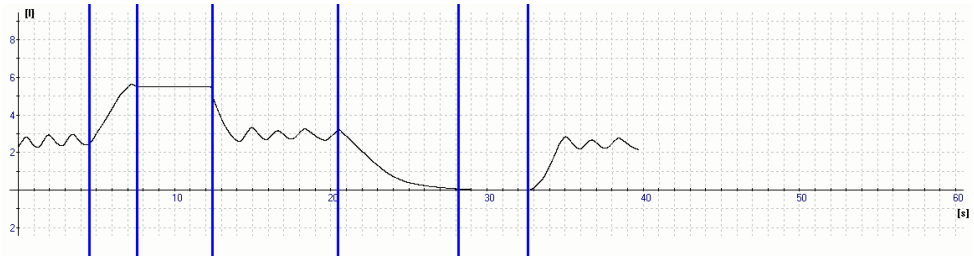
Measurement process

The following series of manoeuvres must be performed:

- Place the nasal clip so the patient can only breathe through the mouth
- Have the patient breathe evenly, relaxed
- Instruct the patient to take a complete, deep breath
- When the patient began the deep inhalation, press the **[Shutter]** button
- Have the patient try to exert as great force as possible exhaling against the shutter; the current mouth pressure value appears on the screen
- Pressing the **[Shutter]** button again opens the shutter immediately
- Have the patient breathe evenly, relaxed again
- Instruct the patient to exhale completely, deep
- When the patient began the deep exhalation, press the **[Shutter]** button
- Have the patient try to exert as great force as possible inhaling against the shutter; the current mouth pressure value appears on the screen
- Pressing the **[Shutter]** button again opens the shutter immediately

Push the **[Done]** button to stop the measurement.

Push the [**Discard**] button to delete the measurement.



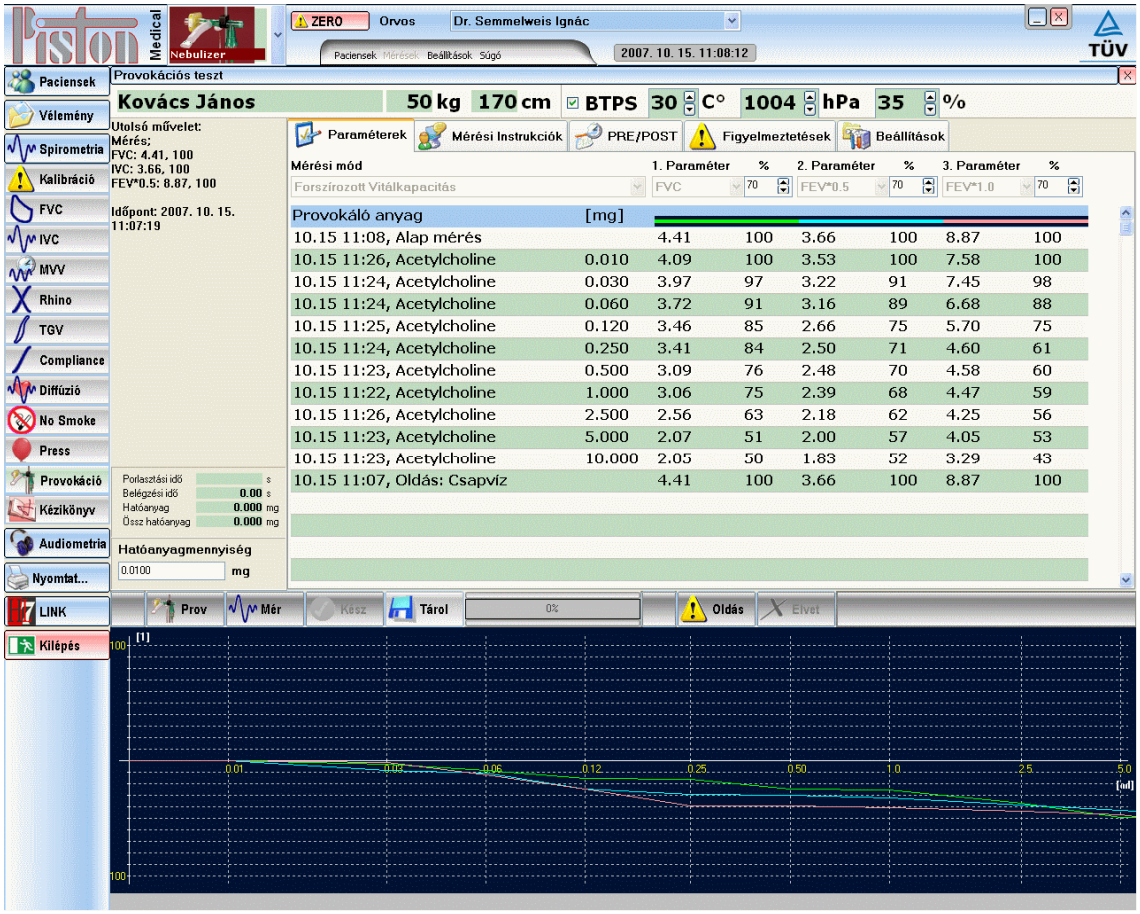
Correct PImax / PEmax measurement
Phases: quiet breathing, complete deep inspiration, PEmax measurement quiet breathing, complete deep expiration, PImax measurement, quiet breathing

Provocation test

S R P D

Measurement goal

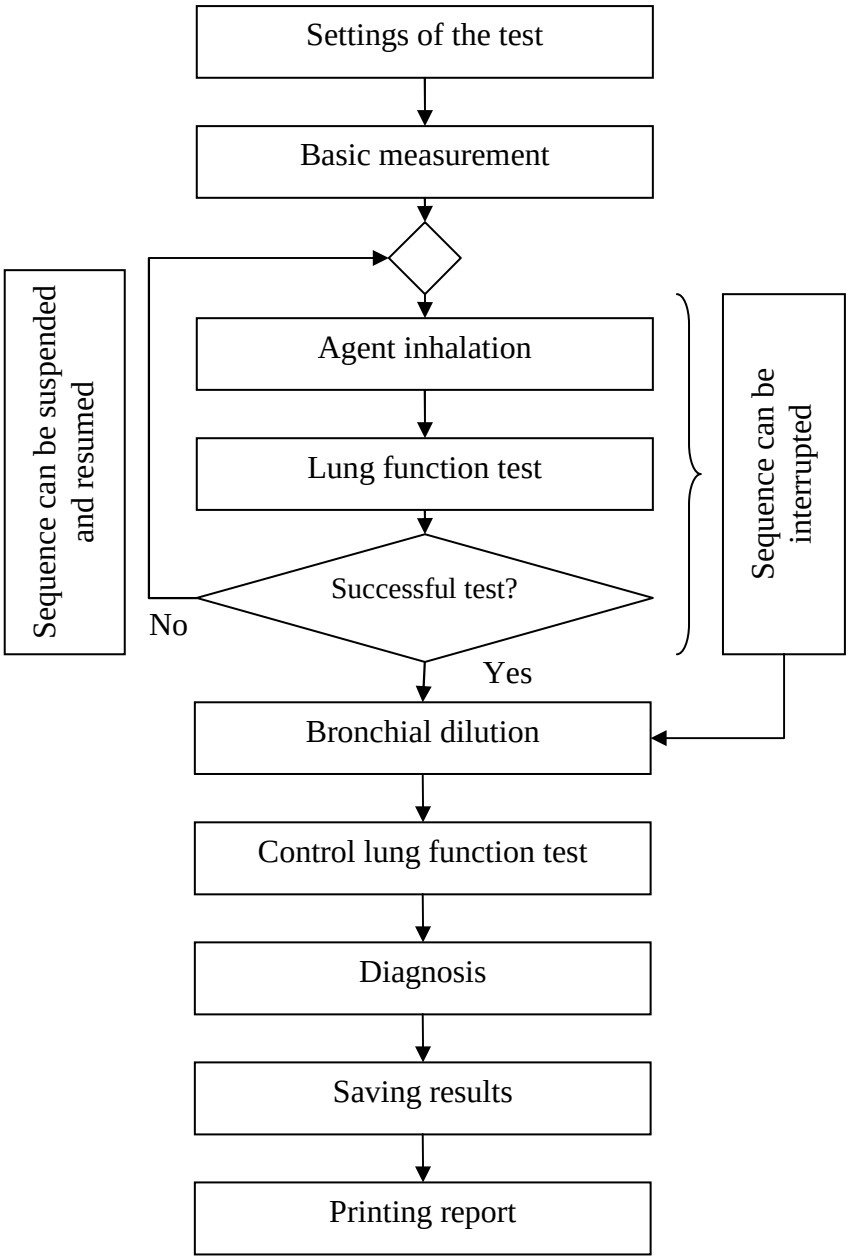
The goal of the measurement is performing a pharmaco-dynamic test, determining effect of inhaled agent on the lung function parameters of the patient.



The result table of the Provocation test contains the following items:

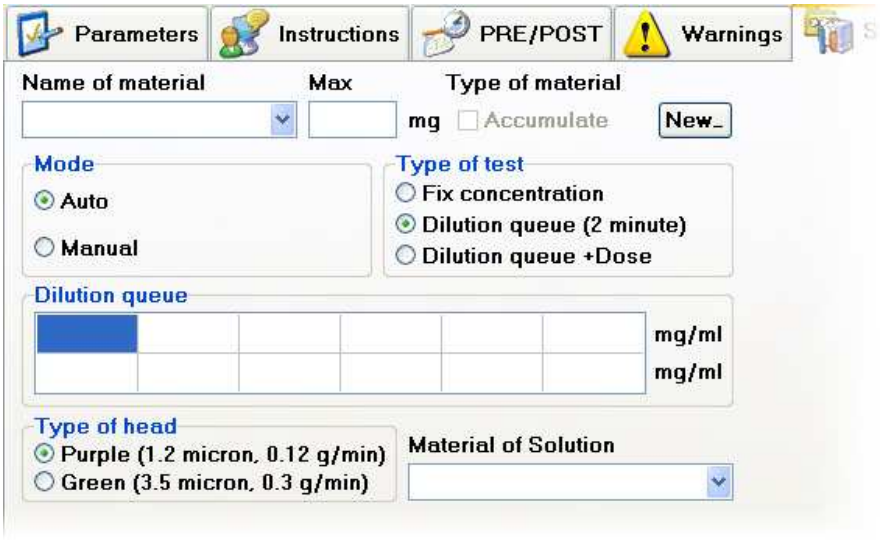
- Time of the measurement (date, hour, minute)
- Name of the provocation and/or diluting agent
- Dose
- Value of the #1 parameter
- Percentage of the #1 parameter to the basic value
- Value of the #2 parameter
- Percentage of the #2 parameter to the basic value
- Value of the #3 parameter
- Percentage of the #3 parameter to the basic value

Provocation flow chart



Setting of Provocation test

Prior to starting a Provocation test parameters should be set, click on the **Settings** tag



Agent's name and properties

Select the provocation agent from the scrolling down list

Value of the maximal dosage in the (Max) field and status of the Accumulate checkbox are retrieved automatically but they can be modified on request

New agent

To enter a new agent click on the [New…] button

Specify the maximal allowed dosage

Specify if the agent has an accumulating effect

Specify the bronchial diluting agent at the Solution section

If you are going to enter only a bronchial diluter you have to leave empty the Material section

To save click on the [Add] button or on the [Cancel] button to abandon changes

Mode

Auto: If the provocation is done by the PDD-301/p dose controlled drug nebuliser

Manual: If the provocation is manually done without dose controlled drug nebuliser

Type of test

There are different kinds of provocation test to select

Fix concentration: Patient inhales more and more dosage from the fix concentration agent

Dilution queue (2 minute): Patient inhales higher and higher concentration from the agent for 2 minutes by occasions

Dilution queue +Dose: Patient inhales increasing concentration and dosage from the agent

Setting the fix concentration

Using the Fix concentration mode the concentration of the agent should be entered in the Concentration field

Setting dilution sequence

Using the Dilution sequence the Dilution queue table should be filled in

Type of nebuliser cup

Using the Auto mode the nebuliser cup has to be selected:

- Purple (1.2 micron, 0.12 g/min) or
- Green (3.5 micron, 0.3 g/min)

Bronchial diluting agent

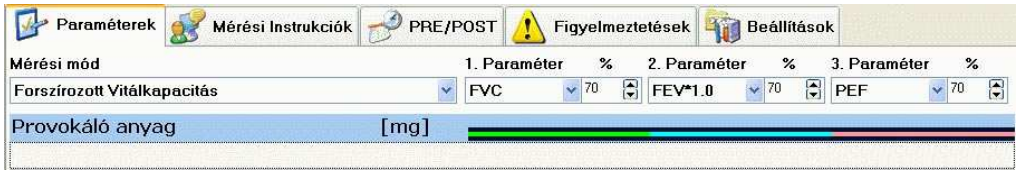
It is strongly advised to finish the provocation test with inhalation of a bronchial diluting agent

Select the bronchial diluting agent from the scrolling down list.

To enter a new bronchial diluting agent click on the [New…] button

Selecting type of lung function test and parameters

To make the provocation sequence simpler and more transparent only one type of lung function tests can be used. The type of lung function tests and the 3 parameters involved should be selected prior to the Basic measure basic measurement.



Lung function test selection

Select the desired type of lung function tests from the Measure Mode scrolling down list

List of the available parameters for the selected type are actualised automatically

Parameter selection

Select the parameters to be followed up from the 1st Parameter, 2nd Parameter, 3rd Parameter scrolling down list

Enter the tolerance limit for each parameter in to the % filed. When any of these limits is reached during the provocation sequence the system gives a warning

Basic measure

The basic measurement should be performed prior to any inhalation from the provocation or bronchial diluting agent. All the following results will be compared to this basic measurement

To start a lung function test click on the [Meas.] button.
The measuring window of the previously selected mode opens.

Perform a few measurements and the Provocation test module selects the best measurement automatically and this will be taken as a Basic measurement as well

After finishing click on the [Provocation] button at the Spirometry main menu and the Provocation test window reappears

☞ Results of the lung function test are stored automatically

Drug nebulising

In the case of Fix concentration and Dilution queue +Dose mode give the actual dosage to be inhale in the Amount of agent field a click on the [Prov] button

Or

In the case of Dilution queue (2 minute) mode click on the [Prov] button

Patient has to inhale evenly from the nebuliser.

The nebulising will be stopped automatically when any of the following conditions is fulfilled:

- The patient inhales the actual dosage (Fix concentration, Dilution queue +Dose)
- The total quantity of the inhaled agent reaches the limit of the agent used
- The nebulising time (Dilution queue (2 minute)) elapsed
- If the process interrupted by clicking on the [Done] button. In this case the already inhaled dosage will be stored

Normally a nebulising cycle should be followed by a lung function test.

In a special need the regular sequence can be overridden and the nebulising can be repeated but a warning appears:

The last maneuver was also nebulizing. Before another nebulization you may do a measure. Do you really want to do another nebulization instead?

If in spite of the warning you follow with nebulising again the inhaled dosage calculated as follows:

- In the case of Accumulate agent the dosage will be summed
- In other case the new dosage is taken into consideration

Measurement cycles

After nebulising a lung function test should be performed in order to check the influence of the inhaled agent.

To start a lung function test click on the [Meas.] button and the previously specified measuring window opens.

Perform a few measurements and the Provocation test module will select the best results automatically

After finishing click on the [Provocation] button at the Spirometry main menu and the Provocation test window reappears.

A message appears giving information on the numbers of performed cycles:

Results of measure imported. Number of Cycles is n.

If the lung function test was omitted a warning appears:

No measurements done!

☞ Results of the lung function test are stored automatically

After a lung function test a new nebulising should be performed.

These cycles should be repeated till the desired effect reached.

If you wish to make a lung function test again in stead of nebulising a warning appears:

The last maneuver was also measuring. Before another measure you may do a nebulization. Do you really want to do another measurement instead?

If any of the selected parameters reaches the previously given limit a message appears:

Provocation successful (list of parameters)

Suspending the sequence

If the reaction time of an agent is too long and there is a need to free the system for other functions the sequence can be suspended at any time.

Click on the [Store] button and close the [Provocation] window

Resuming the sequence

- Search and retrieve the patient from the database (Patient database, page 62)
- Search and retrieve the measurement to be continued from the database, most likely it would be the last one.
- Select a [Provocation] test
- Reload the selected measurement

The a [Provocation] test can be resumed at the next cycle

Bronchial dilution

It is strongly recommended to perform a bronchial dilution after each provocation test in order to prevent the patient from the unexpected effects of the provocation.

Closing the [Provocation] test a warning appears:

WARNING! No solution done yet. Do you really want to exit provocation cycle?

Click on the [Solution] button to store the bronchial dilution.

A lung function test should be performed after the bronchial dilution in order to get evidence of the effectiveness of dilution.

To start a lung function test click on the [Meas.] button and the previously specified measuring window opens.

Perform a few measurements and the Provocation test module will select the best results automatically.

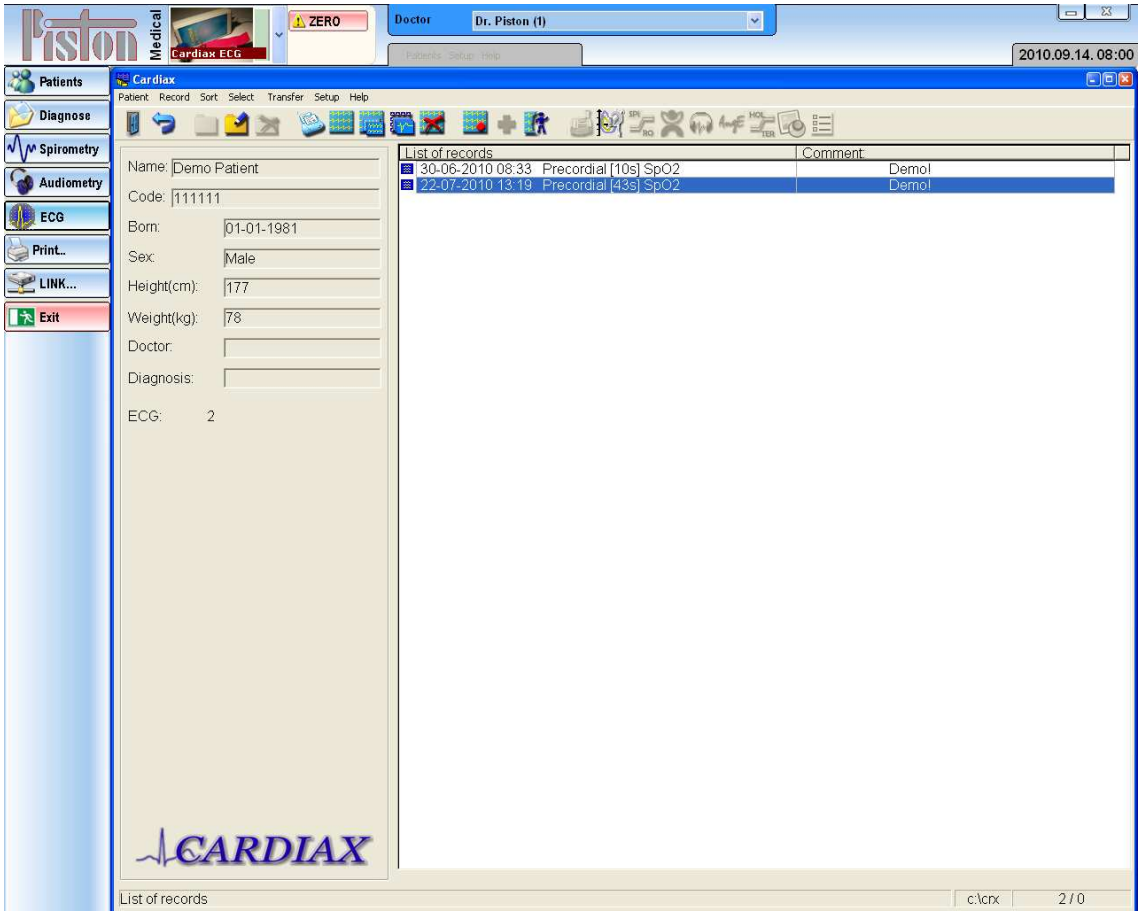
After finishing click on the [Provocation] button at the Spirometry main menu and the Provocation test window reappears.

☞ Results of the lung function test are stored automatically

Electrocardiography

Measurement goal

The software is able to launch and to transfer patient data to the external ECG software Cardiax. So the user is able to maintence a single database while using the services of two different applications.



Measurement process

After select an existing or record a new patient in the database

Launch the IMED Cardiax external ECG software by selecting the ECG option on the Navigator

Follow the instuctions in the Manual of the ECG software to perform ECG recordings

PRE/POST

The PRE/POST measurement

S R P D

The system supports measurement comparison – previous measurements may be compared against measurements made later:

- Select the patient
- Select and load the PRE (or previous) measurements
- Measure the current, POST values with the patient
- Select the two measurement to be compared
- Print the PRE/POST report

Retrieve measurement

Perform the steps in the Patient database (page 62.) section:

- Open the database
- Select the patient
- Select one or more measurements
- Load the measurement results

Max. 8 measurements may be displayed simultaneously, so if you loaded 6 measurements, you can perform 2 more measurements.

Notice

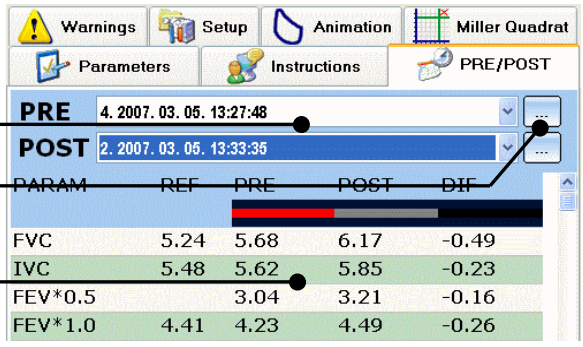
The program also makes it possible to print the PRE/POST report from the actually performed measurements.

Report compilation

Measurement selection

Quick keys

Parameter list



PRE/POST report compilation:

- Select the PRE/POST tab on the measurement window information panel
- Select the two measurements to compare from the measurement selection list
- You can also use the **[Quick keys]** to select the measurement, use the mouse to select the desired

measurement – either from the summary table or directly on the graph
- Selecting the two curves automatically refreshes the parameter table.

Printing

Printing is similar to normal report printing:

- Select the PRE/POST option in the report edit window
- Select the parts of the report you would like to print

During printing the graphs are displayed similar to the screen:

- Complete curve or only the representative curve section
- One or more graphs

TECHNICAL DATA

Warranty

The device complies with the effective Technical Specifications.

The manufacturer guarantees the product according to the terms of the Installation/Delivery protocol.

The warranty does not cover post-delivery careless shipping, unprofessional storage, violent damaging, abnormal operation, unprofessional operation, inefficient protection against external effects, natural disasters, or not following the contents of the User Manual.

Check package condition after delivery.
If packaging is damaged, notify the carrier and Piston Ltd., or its representative.

Limited liability

Piston Ltd. and its carriers, according to the valid laws, do not accept any responsibility for any individual, unforeseeable, direct or indirect damages (including loss of business profit, interruption of business activity, loss of business data, or any other damages due to financial loss), resulting from the use or non-usefulness of the product.

Safety instructions

To avoid possible damages and accidents, please pay attention to the following safety instructions:

- Make sure the mains voltage is the same as that on the product label
- Make sure the connection cable is not damaged
- Take care of your device according to the maintenance section
- Only use the device according to the manual
- Do not use any accessories not recommended for the device
- Store the device in a dry place
- Keep the cable away from heat source, sharp objects, rough surfaces and check the cable's good condition
- Do not expose the device to direct sunlight or strong light (more than 1500 lux)
- Do not use the device in a highly dusty environment
- Do not use the device in a highly vibrating environment
- Take care to ensure the current environmental conditions

The device complies with the contents of the detailed standards in the E section (150 page).

Shipping conditions

Air temperature:.....-30 °C ÷ +60 °C
Relative humidity: .....10% ÷ 100%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Storage conditions

Air temperature:.....0 °C ÷ +50 °C
Relative humidity: .....10% ÷ 85%
Atmospheric pressure: ..... 500 ÷ 1060 mbar

Operating conditions

Air temperature:.....+10 °C ÷ +40 °C
Relative humidity: .....30% ÷ 75%
Atmospheric pressure: ..... 700 ÷ 1060 mbar

Informing values

Expected lifetime

Devices ..... 8 years
Measurement head lifetime ..... 2 years

Forced inhalation and exhalation:

Measurement duration..... 60 s
Volume measurement limit .....15 l

Vital capacity measurement:

Measurement duration..... 60 s
Volume measurement limit .....15 l

Maximal voluntary ventilation:

Measurement duration..... 60 s
Volume measurement limit ..... 250 l/min

Plethysmograph measurement:

Measurement duration..... 60 s
Volume measurement limit ..... 15 l/min
Pressure measurement range .....±10 kPa

Flow meter:

Range.....±15 l/s
Resistance at 10 l/s flow speed.....appr. 30 Pa/l/s
Dead space with bacterial filter .....appr. 180 ml
Heated screen temperature .....34 ºC ÷ 42 ºC
Warm-up time..... 15 minutes

Sampling frequency:

PDD-301 device family..... 100 Hz
PDT-111 device family ..... 250 Hz

Other data:

Analog-digital converter resolution.....12 bit

Electrical data

The connected computer's and printer's electrical data is found in the respective manufacturer provided specifications.

The following values apply only to the Piston Ltd. manufactured devices:

PDD-301/s – Spirometer

PC connection ..... USB 1.1
Power..... Does not require external power

PDD-301/r –Rhinomanometer

PC connection ..... USB 1.1
Power..... Does not require external power

PCD-702 – Combo Device

PC connection ..... USB 1.1
Power..... Does not require external power

PDD-301/sco and PDD-301/rco – Breath CO monitor

PC connection ..... USB 1.1
Power..... Does not require external power

PDD-301/p – Dose controlled drug nebulizer

PC connection .....Optically isolated USB 1.1
Mains voltage ..... 230 VAC
Mains frequency ..... 50~60 Hz
Power consumption 80VA

PDT-111/p – Whole-body Plethysmograph

PC connection .....Optically isolated USB 1.1
Mains voltage ..... 90~264 VAC
Mains frequency ..... 50~60 Hz
Power consumption ..... max. 50 VA

PDT-111/d – Diffusion capacity test

PC connection .....Optically isolated USB 1.1
Mains voltage ..... 90~264 VAC
Mains frequency ..... 50 ÷ 60 Hz
Power consumption ..... max. 50 VA

Mechanical data

PDD-301/s – Spirometer

Flow meter ..... PPF-18 PinkFlow
Dimensions ..... H 150 * W 82 * D 45 mm
Weight ..... 210 g

PDD-301/r – Rhinomanometer

Flow meter ..... PPF-18 PinkFlow
Dimensions ..... H 150 * W 82 * D 45 mm
Weight ..... 210 g

PCD-702 – Combo Device

Flow meter ..... PPF-18 PinkFlow

Headset: ..... TDH 39
Noise attenuation of protecting case: ..... 40 dB
Expected lifetime of the device: ..... 5 years
Step of sound pressure: ..... 5 dB
Frequencies: 125Hz, 250Hz, 500Hz, 750Hz, 1kHz
..... 1,5kHz, 2kHz, 3kHz, 4kHz, 6kHz, 8kHz
Sound pressure level: ..... -10dB HL - +110dBHL

Dimensions ..... H 245 * W 300 * D 45 mm
Weight including headset, electrodes and flowmeter ..... 2.3 kg

For technical data of the ECG see the ECG's documentation

PDD-301/sco and PDD-301/rco – Breath CO monitor

Flow meter ..... PPF-18 PinkFlow
Dimensions ..... H 185 * W 140 * M 60 mm
Weight ..... 650 g

PDD-301/p – Dose controlled drug nebulizer

Dimensions ..... H 260 * W 160 * D 110 mm
Weight 3.5kg

PDT-111/p – Whole-body Plethysmograph

Flow meter ..... Heated stainless steel screen
Reference cabin volume ..... 25 litres

Basic design, PDT-111/p and PDT-111/pd

Cabin dimensions ..... H 1680 * W 925 * D 790 mm
Cabin volume ..... 910 litres
Cabin weight ..... 200 kg

Wheelchair design, PDT-111/pwc

Cabin dimensions ..... H 1680 * W 925 * D 1240 mm
Cabin volume ..... 1160 litres
Cabin weight ..... 240 kg

PDT-111/d – Diffusion capacity test

Flow sensor ..... Heated stainless steel screen
Gas mixture ..... CO 0,3%, CH4 0,3% and synthetic air
Gas cylinder ..... 10-liter aluminium
Dimensions (without patient circuit) H 250 * W 475 * D 155mm
Weight (without patient circuit) ..... 5,6 kg
Gas analyzer ..... multi-channel fast NDIR

Guaranteed values

PPF-18 – PinkFlow flow meter

Type PPF-18
Principle of operation ..... Symmetric Pitot tube
Flow range ..... ±18 l/s
Dead space ..... 36 ml
Resistance ..... 60 Pa/l/s @ 15 l/s
Weight ..... 34 gramm

PDD-301 – Spirometer and Rhinomanometer

Flow meter ..... PPF-18 PinkFlow
Flow measurement range ..... ±18 l/s
Flow measurement accuracy ..... ±3% or ±50 ml/s
Volume measurement range ..... 185 l
Volume measurement accuracy ..... ±3% or ±50 ml

PCD-702 – Combo Device

Flow meter ..... PPF-18 PinkFlow

Total harmonic distortion: ..... < 1%
Accuracy of frequency: ..... ±1%

For technical data of the ECG see the ECG's documentation

PDD-301/r – Rhinomanometer

Flow meter ..... PPF-18 PinkFlow
Pressure measurement range ..... ±2 kPa
Pressure measurement accuracy ..... ±3% or ±15 Pa
Resistance measurement accuracy ..... ±3% or ±30 Pa/l/s

PDD-301/sco – Breath CO monitor and spirometer

Accuracy of CO measurement ..... ±2% or ±2 ppm
All other measurement parameters are the same as of the PDD-301/s spirometer

PDD-301/rco – Breath CO monitor and rhinomanometer

Accuracy of CO measurement ..... ±2% or ±2 ppm
All other measurement parameters are the same as of the PDD-301/r rhinomanometer

PDD-301/p – Dose controlled drug nebulizer

IS-1501 – Green vaporizing head:
Vaporizing particle size ..... 3,5 micron 90%
Vaporizing power .....0,3 g/min

IS-1503 – Purple vaporizing head:
Vaporizing particle size ..... 1,2 micron 90%
Vaporizing power .....0,12 g/min
Compressor power..... 8 l/s output @ 2,5 bar

PDT-111/p – Whole-body Plethysmograph

Flow measurement range ..... ±15 l/s
Flow measurement accuracy .....±3% or ±50 ml/s
Volume measurement range..... 15 l
Volume measurement accuracy.....±3% or ±50 ml
Pressure measurement range.....±10 kPa
Pressure measurement accuracy.....±3% or ±50 Pa
Resistance measurement accuracy .....±3% or ±50 Pa/l/s
TLC, RV volume measurement accuracy .....±5% or ±100 ml
Time measurement accuracy ..... 4 ms
Recommended nr. of breaths, large time constant ....20 - 40 / min
Recommended nr. of breaths, small time constant. 60 - 120 / min

PDT-111/pd – Diffusion capacity test

Flow measurement range ..... ±15 l/s
Flow measurement accuracy.....±3 % or ±100 ml/s
Volume measurement range..... 15 l
Volume measurement accuracy ..... ±3 % or ±50 ml
Gas concentration measurement accuracy..... ±5%
FRC, RV volume measurement accuracy .....±5% or ±100 ml

List of accessories

Included accessories

The current Shipping contract contains the list of accessories included in the purchase price.

Optionally purchased accessories

The following information must be provided when ordering accessories and disposables:

- Description
- Type
- Part number
- Device type and serial number for which the accessories are used

EMC GUIDANCE AND MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer) is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD 301/r** Rhinomanometer should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The **PDD 301/r** Rhinomanometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **PDD 301/r** Rhinomanometer is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity

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IMMUNITY test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **<5 % U_T** (>95 % dip in U_T) for 5 s	**Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **PDD 301/r** Rhinomanometer requires continued operation during power mains interruptions, it is recommended that the **PDD 301/r** Rhinomanometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer) is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD 301/r** Rhinomanometer should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 0,15-80 MHz	3 V_{rms} 0,15-80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **PDD 301/r** Rhinomanometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5GHz	3 V/m 80MHz – 2,5GHz	$d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PDD 301/r** Rhinomanometer is used exceeds the applicable RF compliance level above, the **PDD 301/r** Rhinomanometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PDD 301/r** Rhinomanometer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PDD 301/r Rhinomanometer

The **PDD 301/r** Rhinomanometer (particular implementation **PDD 301/s** Spirometer)is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of **PDD 301/r** Rhinomanometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PDD 301/r** Rhinomanometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,38
100	11,7	11,7	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **<5 % U_T** (>95 % dip in U_T) for 5 s	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test requires continued operation during power mains interruptions, it is recommended that the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 0,15-80 MHz	3 V_{rms} 0,15-80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5GHz	3 V/m 80MHz – 2,5GHz	$d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test is used exceeds the applicable RF compliance level above, the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PDT 111/pd Whole body plethysmograph and Diffusion capacity test

The **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PDT 111/pd** Whole body plethysmograph and Diffusion capacity test as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,38
100	11,7	11,7	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The **PDD-301/p** drug nebuliser is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD-301/p** drug nebuliser should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **PDD-301/p** drug nebuliser uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **PDD-301/p** drug nebuliser is suitable for use in all establishments, including domestic establishments and those directly connected to the public lowvoltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDD-301/p** drug nebuliser is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD-301/p** drug nebuliser should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **<5 % U_T** (>95 % dip in U_T) for 5 s	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **PDD-301/p** drug nebuliser requires continued operation during power mains interruptions, it is recommended that the **PDD-301/p** drug nebuliser be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The **PDD-301/p** drug nebuliser is intended for use in the electromagnetic environment specified below. The customer or the user of the **PDD-301/p** drug nebuliser should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 0,15-80 MHz	3 V_{rms} 0,15-80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **PDD-301/p** drug nebuliser, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5GHz	3 V/m 80MHz – 2,5GHz	$d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PDD-301/p** drug nebuliser is used exceeds the applicable RF compliance level above, the **PDD-301/p** drug nebuliser should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PDD-301/p** drug nebuliser.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PDD-301/p drug nebuliser

The **PDD-301/p** drug nebuliser is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **PDD-301/p** drug nebuliser can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PDD-301/p** drug nebuliser as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,38
100	11,7	11,7	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The **PRE-101** Ergospirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the **PRE-101** Ergospirometer should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The **PRE-101** Ergospirometer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The **PRE-101** Ergospirometer is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The **PRE-101** Ergospirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the **PRE-101** Ergospirometer should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **<5 % U_T** (>95 % dip in U_T) for 5 s	**<5 % U_T** (>95 % dip in U_T) for 0,5 cycle **40 % U_T** (60 % dip in U_T) for 5 cycles **70 % U_T** (30 % dip in U_T) for 25 cycles **Not applicable**	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **PRE-101** Ergospirometer requires continued operation during power mains interruptions, it is recommended that the **PRE-101** Ergospirometer be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The **PRE-101** Ergospirometer is intended for use in the electromagnetic environment specified below. The customer or the user of the **PRE-101** Ergospirometer should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 0,15-80 MHz	3 V_{rms} 0,15-80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the **PRE-101** Ergospirometer, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2,5GHz	3 V/m 80MHz – 2,5GHz	$d = 1{,}17\sqrt{P}$ *80 MHz to 800 MHz* $d = 2{,}33\sqrt{P}$ *800 MHz to 2,5 GHz* where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **PRE-101** Ergospirometer is used exceeds the applicable RF compliance level above, the **PRE-101** Ergospirometer should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **PRE-101** Ergospirometer.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the PRE-101 Ergospirometer

The **PRE-101** Ergospirometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **PRE-101** Ergospirometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **PRE-101** Ergospirometer as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz – 80 MHz $d = 1{,}17\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}17\sqrt{P}$	**800 MHz – 2,5 GHz** $d = 2{,}33\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,7	3,7	7,38
100	11,7	11,7	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CERTIFICATES OF QUALITY MANAGEMENT SYSTEM

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland Product Safety GmbH

hereby certifies that the organization

Piston Kft.
Pihenö u. 1/C
1121 Budapest
Hungary

has established and applies a quality management system for medical devices for the following scope:

Production and sales of audiometer and of lung diagnostic equipment and connecting single use mouth-piece and bacteria filter

Proof has been furnished that the requirements specified in

EN ISO 13485:2003

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SX 60017406 0001

An audit was performed. Report No.: 28202723 002

This Certificate is valid until: 20.12.2011

Certification Body

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-995.00.01-46

TÜV Rheinland Product Safety GmbH
TÜV Rheinland
Zertifizierungsstelle

Cologne, 20.03.2007

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Tel.: (+49/221) 806 - 1371 Fax: (+49/221) 806 - 3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

10/020 12 06Q

TÜVRheinland®

APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60017404 0001

Report No.: 28202723 002

Manufacturer:

Piston Kft.
Pihenö u. 1/C
1121 Budapest
Hungary

Scope:

Production and sales of audiometer and of
lung diagnostic equipment and connecting
single use mouth-piece and bacteria filter

Replaces Approval, Registration No.: HD 2111265 01

Date of Expiry: 20.12.2011

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland Product Safety GmbH TÜV Rheinland Zertifizierungsstelle

Cologne, 20.03.2007

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

10/020 12.06Q

EC DECLARATION OF CONFORMITY

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Spirometer, IBM/PC based

MODEL NUMBER

PDD-301/s

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/

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Kornél NAGY, Mr
Quality Assurance Manager

PISTON Kft. Adószám: 10465905-2-41 1021 Bp., Budakeszi út 47/c. 1225 Bp., Pihenő út 1/c.

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Dose controlled drug nebulizer, IBM/PC based

MODEL NUMBER

PDD-301/p

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
H-1033 Budapest
Szőlőkert u. 4/b
HUNGARY

Tel: +36-1-275-0033
Fax: +36-1-275-0034
http: www.pistonmedical.com
Email: info@pistonmedical.com

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1033, Budapest, Szőlőkert u. 4/b

PRODUCT

Breath carbon monoxide monitor

MODEL NUMBER

PDD-301/sco and PDD-301/rco

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex IX

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1:2005
EN 60601-1-1:2001
EN 60601-1-2:2001
EN 60601-1-4:1996
EN 60601-1-6:2004
EN 980:2003
EN 1041:1998
ISO 14971:2000

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Grauen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 60009710 0001
	Report Nr:	02192133 004
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 25 AUG 2008/

PISTON Kft 1033 Budapest Szőlőkert u 4/b Adószám: 10465905-2-41

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Rhinomanometer and Spirometer, IBM/PC based

MODEL NUMBER

PDD-301/r

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

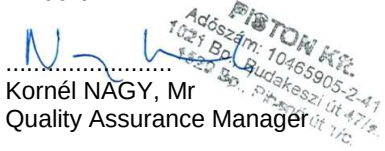
EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/



.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Whole-body plethysmograph

MODEL NUMBER

PDT-111/p

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197		
Safety test	Report Nr:	28203472001
EMC test	Report Nr:	28203473001

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Diffusion capacity test

MODEL NUMBER

PDT-111/d

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197		
Safety test	Report Nr:	28203472001
EMC test	Report Nr:	28203473001

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Whole-body plethysmograph and Diffusion capacity test

MODEL NUMBER

PDT-111/pd

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197		
Safety test	Report Nr:	28203472001
EMC test	Report Nr:	28203473001

MAIN ACCESSORIES

PCS-3000	Calibration syringe
PBF-30	Bacterial filter
MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/

PISTON Kft. Adószám: 10465905-2-41 1021 Budakeszi út 47/a

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Calibration Syringe for spirometers

MODEL NUMBER

PCS-3000

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Grauen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

BUDAPEST, 12TH JUNE 2007

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Kft. Adószám: 10465905-2-41 1021 Budakeszi út 47/a. 1121 Bp., Pihenő út 1/c.

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Bacterial and viral filter for spirometry

MODEL NUMBER

PBF-30SU

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

MPA-30	Mouth piece

BUDAPEST, 11 MAY 2007/

PISTON Kft. Adószám: 10465905-2-41 1021 Budakeszi út 47/a. 1121 Bp., Pihenő u. 1/c.

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Mouthpiece for spirometry

MODEL NUMBER

MPA-30

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

PBF-30SU	Bacterial and viral vilter

BUDAPEST, 11 MAY 2007/

PISTON Kft. Adószám: 10465905-2-41 1021 Budakeszi út 47/a. 1121 Bp., Pihenő u. 1/c.

.....
Kornél NAGY, Mr
Quality Assurance Manager

PISTON Ltd.
1121 Budapest
Pihenő u. 1. C pavilon
HUNGARY

Tel: **+36-1-275-0033**
Fax: **+36-1-275-0034**
http: **www.pistonmedical.com**
Email: **info@pistonmedical.com**

EC DECLARATION OF CONFORMITY

MANUFACTURER

Piston Ltd.
Hungary, H-1121, Budapest, Pihenő u. 1/c

PRODUCT

Nasal probe for rhinomanometer

MODEL NUMBER

PNP-12, PNP-14, PNP-16 different sizes

CLASSIFICATION

Class IIa
Council Directive 93/42/EEC of MDD, Annex V, Article 3

DECLARATION

We herewith declare that the above mentioned products meet the provision of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer

STANDARDS APPLIED

EN 60601-1
EN 60601-1-2
EN 30993-1
EN 980
EN 1441

NOTIFIED BODY

TÜV Rheinland Product Safety GmbH
Germany, D-51105 Köln, Am Garuen Stein

EC CERTIFICATES

ISO 13485:2003	Registration Nr:	SX 600174060001
	Report Nr:	28202723002
CE 0197	Registration Nr:	HD 2111265 01
	Report Nr:	C 2192133 E 01

MAIN ACCESSORIES

Not specified

BUDAPEST, 11 MAY 2007/

PISTON Kft. Adószám: 10465905-2-41 1021 Budakeszi út 47/a. 1121 Bp., Pihenő u. 1/c.

.....
Kornél NAGY, Mr
Quality Assurance Manager

APPENDIX I.

List of reference value algorithms:

- ECCS/ERS (Quanjer, 1993)
- Knudson, 1983
- Cotton and Dust Standard
- Crapo-Hsu
- Austrian National
- Sweden National (Hedenström / Malmberg, 1985)
- Finnish National (Viljanen, 1981)

On special request new reference value algorithms can be added to the system.

European Community for Coal and Steel

„Standardized Lung Function Testing" by European Community for Coal and Steel published in 1983:

Male:

TLC	[l]	7.99H- 7.08	0.70 RSD
RV	[l]	1.31H+0.022A-1.23	0.41 RSD
FRC	[l]	2.34H+0.009A-1.09	0.60 RSD
RV/TLC	[%]	0.39A+13.96	5.46 RSD
IVC	[l]	6,10H - 0,028A - 4,65	0,56 RSD
FVC	[l]	5,76H - 0,026A - 4,34	0,61 RSD
FEV*1,0	[l]	4,30H - 0,029A - 2,49	0,51 RSD
FEV*1,0/IVC	[%]	-0,18 A + 87,21	7,17 RSD
FEF*25-75%	[l/s]	1,94H - 0,043A + 2,70	1,04 RSD
PEF	[l/s]	6,14H - 0,043A + 0,15	1,21 RSD
FEF*75%	[l/s]	5,46H - 0,029A - 0,47	1,71 RSD
FEF*50%	[l/s]	3,79H - 0,031A - 0,35	1,32 RSD
FEF*25%	[l/s]	2,61H - 0,026A - 1,34	0,78 RSD
Raw	[kPa/l/s]	<<0.22 (fupper limit)	
sGaw	[1/kPa/s]	>>0.85 (lower limit)	
Tlco	[mmol/min/kPa]	11.11H-0.066A-6.03	1.41 RSD
Klco	[mmol/min/kPa/l]	-0.011A+2.43	0.27 RSD

Where:

A	age:	18 years ÷.70 years
H	height:	155 cm ÷ 195 cm

Female:

TLC	[l]	6.60H-5.79	0.60 RSD
RV	[l]	1.81H+0.016A-2.00	0.35 RSD
FRC	[l]	2.24H+0.001A-1.00	0.50 RSD
RV/TLC	[%]	0.34A+18.96	5.83 RSD
IVC	[l]	4,66H - 0,024A - 3,28	0,42 RSD
FVC	[l]	4,43H - 0,026A - 2,89	0,43 RSD
FEV*1,0	[l]	3,95H - 0,025A - 2,69	0,38 RSD

FEV*1,0/IVC	[%]	-0,19 A + 89,10	6,51 RSD
FEF*25-75%	[l/s]	1,25H - 0,034A + 2,92	0,85 RSD
PEF	[l/s]	5,50H - 0,030A + 1,11	0,90 RSD
FEF*75%	[l/s]	3,22H - 0,025A - 1,60	1,35 RSD
FEF*50%	[l/s]	2,45H - 0,025A - 1,16	1,10 RSD
FEF*25%	[l/s]	1,05H - 0,025A - 1,11	0,69 RSD
Raw	[kPa/l/s]	<<0.22 (fupper limit)	
sGaw	[1/kPa/s]	>>1.04 (lower limit)	
Tlco	[mmol/min/kPa]	8.18H-0.049A-2.74	1.17 RSD
Klco	[mmol/min/kPa/l]	-0.004A+2.24	0.49 RSD

Where:

A	age:	18 years ÷ 70 years
H	height:	145 cm ÷ 180 cm

Reference values for children from "Pulmonology Child Care" by G.K. Arotock published in 1984.

Boys:

IVC	[l]	0,0405H + 0,051A - 3,65H
FVC	[l]	0,00542H + 0,2049A - 0,3306
FEV*0,5	[l]	0,0299H - 2,98
FEV*1,0	[l]	0,04H - 3,99
FEV*1,0/IVC	[%]	1,09H - 4,897A - 35,58
PEF	[l/s]	0,0823H - 6,87
FEF*50%	[l/s]	0,0543H - 4,58
FEF*25%	[l/s]	0,0282H - 2,31

Girls:

IVC	[l]	0,0279H + 0,0909A - 2,554H
FVC	[l]	0,088H + 0,1307A - 0,3761
FEV*0,5	[l]	0,0299H - 2,98
FEV*1, 0	[l]	0,04H - 3,99
FEV*1,0/IVC	[%]	1,23H - 4,48A - 37,83
PEF	[l/s]	0,0823H - 6,87
FEF*50%	[l/s]	0,0448H - 3,37
FEF*25%	[l/s]	0,0248H - 1,86

Where:

A	age:	6 years ÷.18 years
H	height:	110 cm ÷ 185 cm

Knudson

January 1984
F: female
M: male
H: height centimetre
A: age year

NORM	SEX	Age	Equation	95% C.I
FVC	F	6-10	0.0430M - 3.7486	
	F	11-19	0.0416M - 4.4470 + 0.0699A	
	F	20-69	0.0444M - 3.1947 - 0.0169A	
	F	>=70	0.0313M - 0.1889 - 0.0296A	
	M	6-11	0.0409M - 3.3756	
	M	12-24	0.0590M - 6.8865 + 0.0739A	
	M	>=25	0.0844M - 8.7818 - 0.0298A	
FEV0.5	F	20	0.061A + 0.048H - 1.738	1.03
	F	150	-0.014A + 0.048H - 0.406	0.85
	M	25	0.043A + 0.076H - 3.054	1.43
	M	150	-0.017A + 0.094H - 2.746	1.13
FEV0.5/FVC	A	150	Divide Predicteds	
FEV1	F	6-10	0.0336M - 2.7578	
	F	11-19	0.0351M - 3.7622 + 0.0694A	
	F	20-69	0.0332M - 1.8210 - 0.0190A	
	F	>=70	0.0143M + 2.6539 - 0.0397A	
	M	6-11	0.0348M - 2.8142	
	M	12-24	0.0519M - 6.1181 + 0.0636A	
	M	>=25	0.0665M - 6.5147 - 0.0292A	
FEV1/FVC	F	150	(-0.00109A-0.00282H+1.0738)x100	
	M	150	(-0.0014A - 0.00221H + 1.0364)x100	
FEF 25-75%	F	6-10	0.0220M - 0.8119	
	F	11-19	0.0279M - 2.8007 + 0.1275A	
	F	20-69	0.0300M - 0.4057 - 0.0309A	
	F	>=70	6.3706 - 0.0615A	
	M	6-11	0.0338M - 2.3197	
	M	12-24	0.0539M - 6.1990 + 0.0749A	
	M	>=25	0.0579M - 4.5175 - 0.0363A	
FEF 25%	F	20	0.144A + 0.112H - 3.365	
	F	150	-0.025A + 0.109H - 0.132	
	M	25	0.147A + 0.1778H - 7.054	
	M	150	-0.035A + 0.223H - 5.618	
FEF 50%	F	6-10	0.7362 + 0.1846A	1.17
	F	11-19	0.0238M - 2.3040 + 0.1111A	1.76
	F	20-69	0.0321M - 0.4371 - 0.0240A	1.81
	F	>=70	0.0118M + 6.2402 - 0.0755A	1.34
	M	6-11	0.0378M - 2.5454	1.30
	M	12-24	0.0543M - 6.3851 + 0.1150A	2.47
	M	>=25	0.0634M - 5.5409 - 0.0366A	2.67
FEF 75%	F	6-10	0.0109M - 0.1657	0.83
	F	11-19	0.0243M - 4.4009 + 0.1775A	1.25
	F	20-69	0.0174M - 0.1822 - 0.0254A	1.35

PEF	F	20	0.157A + 0.1244H - 3.916	
	F	150	-0.025A + 0.1244H - 0.735	
	M	25	0.166A + 0.198H - 8.06	
	M	150	-0.035A + 0.2387H - 5.993	
FIVC	F	6-10	0.0430M - 3.7486	
	F	11-19	0.0416M - 4.4470 + 0.0699A	
	F	20-69	0.0444M - 3.1947 - 0.0169A	
	F	>=70	0.0313M - 0.1889 - 0.0296A	
	M	6-11	0.0409M - 3.3756	
	M	12-24	0.0590M - 6.8865 + 0.0739A	
	M	>=25	0.0844M - 8.7818 - 0.0298A	
MVV	A	18	3.241H - 99.51	
	F	150	-0.77A + 138	32.80
	M	150	-1.26A + 3.39H - 21.4	55.76
VC	F	6-10	0.0430M - 3.7486	
	F	11-19	0.0416M - 4.4470 + 0.0699A	
	F	20-69	0.0444M - 3.1947 - 0.0169A	
	F	>=70	0.0409M - 3.3756	
	M	12-24	0.0590M - 6.8865 + 0.0739A	
	M	>=25	0.0844M - 8.7818 - 0.0298A	
TLC	F	18	0.2493M - 5.101	
	F	150	-0.008A + 0.201H - 7.49	0.767
	M	25	0.1495H - 5.034	
	M	250	-0.015A + 0.239H - 9.17	0.999
RV	A	18	0.029H - 0.9292	
	F	150	0.009A + 0.0813H - 3.9	0.705
	M	150	0.017A + 0.0686H - 3.45	0.790
RV/TLC	A	18	Divide Predicteds	
	F	150	(0.00265A + 0.217) x 100	11.73
	M	150	(0.00343A + 0.167) x 100	12.02
Raw	F	=17	7.143 / (Vtg + 0.49)	
	F	=18	3.45 / (Vtg - 0.27)	
	M	=17	7.143 / (Vtg + 0.49)	
	M	=18	3.57 / (Vtg - 0.73)	
Gaw	A	=18	0.24 x Vtg	
	F	7-17	0.227 - 0.041 x Vtg	
	M	7-17	0.227 - 0.041 x Vtg	
sRaw	F	=17	7.143 - 0.49 Pred Raw	
	F	=18	3.45 + 0.27 Pred Raw	
	M	=17	7.143 - 0.49 Pred Raw	
	M	=18	3.57 + 0.73 Pred Raw	
DLCO	A	17	Antilog10 (0.01666H + 0.308)	
	F	150	-0.117A + 15.5BSA + 0.5	6.0
	M	50	-0.238A + 15.5BSA + 6.8	8.2

Cotton and Dust Standard

January 1984

F: female
M: male
H: height - centimetre
A: age - year

NORM	SEX	Age	Equation	95% C.I
FVC	F	20	0.92A + .08382H - 3.469	1.64
	F	150	-0.022A + 0.094H - 1.774699A	1.26
	M	25	0.078A + 0.127H - 5.5080169A	2.35
	M	150	-0.029A + 0.165H - 5.459296A	1.71
FEV0.5	F	20	0.061A + 0.048H - 1.738	1.03
	F	150	-0.014A + 0.048H - 0.406	0.85
	M	25	0.043A + 0.076H - 3.054	1.43
	M	150	-0.017A + 0.094H - 2.746	1.13
FEV0.5/FVC	A	150	Divide Predicteds	
FEV1	F	20	0.85A + 0.06852H - 2.703	1.39
	F	150	-0.021A + 0.069H - 0.794	1.12
	M	25	0.045A + 0.117H - 4.808	1.95
	M	150	-.027A + .132H - 4.203	1.51
FEV1/FVC	F	150	(-0.00109A - 0.00282H + 1.0738)x100	
	M	150	(-0.0014A - 0.00221H + 1.0364)x100	
FEF 25-75%	F	6-10	0.0220M - 0.8119	
	F	11-19	0.0279M - 2.8007 + 0.1275A	
	F	20-69	0.0300M - 0.4057 - 0.0309A	
	F	>=70	6.3706 - 0.0615A	
	M	6-11	0.0338M - 2.3197	
	M	12-24	0.0539M - 6.1990 + 0.0749A	
	M	>=25	0.0579M - 4.5175 - 0.0363A	
FEF 25%	F	20	0.144A + 0.112H - 3.365	
	F	150	-0.025A + 0.109H - 0.132	
	M	25	0.147A + 0.1778H - 7.054	
	M	150	-0.035A + 0.223H - 5.628	
FEF 50%	F	6-10	0.7362 + 0.1846A	1.17
	F	11-19	0.0238M - 2.3040 + 0.1111A	1.76
	F	20-69	0.0321M - 0.4371 - 0.0240A	1.81
	F	>=70	0.0118M + 6.2402 - 0.0755A	1.34
	M	6-11	0.0378M - 2.5454	1.30
	M	12-24	0.0543M - 6.3851 + 0.1150A	2.47
	M	>=25	0.0634M - 5.5409 - 0.0366A	2.67
FEF 75%	F	6-10	0.0109M - 0.1657	0.836
	F	11-19	0.0243M - 4.4009 + 0.2923A	1.25
	F	20-69	0.0174M - 0.1822 - 0.0254A	1.35
	F	>=70	1.8894 - 0.0172A	0.41
	M	6-11	0.0171M - 1.0149	0.89
	M	12-24	0.0397M - 4.2421 - 0.0057A	1.46
	M	>=25	0.0310M - 2.4824 - 0.0230A	1.45
PEF	F	20	0.257A + 0.2244H - 3.926	

	F	150	-0.025A + 0.1244H - 0.735	
	M	25	0.266A + 0.198H - 8.06	
	M	150	-0.035A + 0.2387H - 5.993	
FIVC	F	20	0.092A + 0.8382H - 3.469	1.64
	F	150	-0.022A + 0.094H - 1.774	1.26
	M	25	0.078A + 0.127H - 5.508	2.35
	M	150	-0.029A + 0.165H - 5.459	1.71
MVV	A	18	3.241H - 99.51	
	F	150	-0.77A + 138	32.80
	M	150	-1.26A + 3.39H - 21.4	55.76
VC	F	20	0.092A + 0.08382H - 3.469	1.64
	F	150	-0.022A + 0.094H - 1.774	1.26
	M	25	0.078A + 0.127H - 5.508	2.35
	M	150	-0.029A + 0.165H - 5.549	1.71
TLC	F	18	0.1493M - 5.101	
	F	150	-0.008A + 0.201H - 7.49	0.767
	M	18	0.1495H - 5.034	
	M	150	-0.015A + 0.239H - 9.17	0.999
RV	A	18	0.029H - 0.9192	
	F	150	0.009A + 0.0813H - 3.9	0.705
	M	150	0.017A + 0.0686H - 3.45	0.790
RV/TLC	A	18	Divide Predicteds	
	F	150	(0.00265A + 0.217) x 100	11.73
	M	150	(0.00343A + 0.167) x 100	12.02
Raw	F	<=17	7.143 / (Vtg + 0.49)	
	F	>=18	3.45 / (Vtg - 0.27)	
	M	<=17	7.143 / (Vtg + 0.49)	
	M	>=18	3.57 / (Vtg - 0.73)	
Gaw	A	<=18	0.24 x Vtg	
	F	7-17	0.227 - 0.041 x Vtg	
	M	7-17	0.227 - 0.041 x Vtg	
sRaw	F	<=17	7.143 - 0.49 Pred Raw	
	F	>=18	3.45 + 0.27 Pred Raw	
	M	<=17	7.143 - 0.49 Pred Raw	
	M	>=18	3.57 + 0.73 Pred Raw	

Crapo-Hsu

April 1984

F: female
M: male
H: height - centimetre
A: age - year

NORM	SEX	Age	Equation	95% C.I
FVC	M	15-91	0.0600M - 0.0214A - 4.650	1.00
	M	15	3.58 x 10 -4 x M	3.18
	F	15-91	0.0491M - 0.0216A - 3.590	0.67
	F	15	2.57 x 10 -3 x M	2.78
FEV 0.5	M	15-91	0.0327M - 0.0152A - 1.914	0.70
	F	15-91	0.0238M - 0.0185A - 0.809	0.50
FEV 1.0	M	15-91	0.0414M - 0.0244A - 2.190	0.80
	M	15	7.74 x 10 -4 x M	3.00
	F	15-91	0.0342M - 0.0255A - 1.578	0.56
	F	15	3.79 x 10 -3 x M	2.68
FEV1/FVC%	M	15-91	-0.1300M - 0.152A + 110.49	8.28
	F	15-91	-0.2020M - 0.252A + 126.58	9.06
FEF 25-75%	M	15-91	0.0204M - 0.0380A + 2.133	1.66
	M	15	7.98 x 10 -4 x M	2.46
	F	15-91	0.0154M - 0.0460A + 2.683	1.36
	F	15	3.79 x 10 -3 x M	2.16
PEF	M	15	3.35 x 10 -4 x M	2.79
	F	15	2.58 x 10 -3 x M	2.37
FIVC	M	15-91	0.0600M - 0.0214A - 4.650	1.10
	M	15	3.58 x 10 -4 x M	3.18
	F	15-91	0.0491M - 0.0216A - 3.590	0.60
	F	15	2.57 x 10-3 x M	2.78
TLC	M	15-91	0.0795 + 0.0032A - 7.333	1.60
	M	15 11	0.1495H - 5.034	
	F	15-91	0.0590M - 4.537	1.00
	F	15	0.1493H - 5.101	
RV	A	15	0.029H - 0.9192	
	M	15-91	0.0216M + 0.0207A - 2.840	0.76
	F	15-91	0.0197M + 0.0201A - 2.421	0.77
RV/TLC	A	15	Divide Predicteds	
	M	15-91	0.3090A + 14.060	9.80
	F	15-91	0.4160A + 14.350	11.00
VC	M	15-91	0.0600M - 0.0214A - 4.650	1.11
	M	15	3.58 x 10-4 x M	3.18
	F	15-91	0.0491M - 0.0216A - 3.590	0.67
	F	15	2.57 x 10 -3 x M	2.78
Raw	M	<=17	7.143 / (Vtg + 0.49)	
	M	>=18	3.57 / (Vtg - 0.73)	
	F	<=17	7.143 / (Vtg + 0.49)	
	F	>=18	3.45 / (Vtg - 0.27)	
Gaw	A	<=18	0.24 x Vtg	

	M	7-17	0.227 - 0.041 x Vtg
	F	7-17	0.227 - 0.041 x Vtg
sRaw	M	<=17	7.143 - 0.49 Pred Raw
	M	>=18	3.57 + 0.73 Pred Raw
	F	<=17	7.143 - 0.49 Pred Raw
	F	>=18	3.45 + 0.73 Pred Raw

Austrian National

H: height metre
A: age year
W: weight kg
Fi = H/$\sqrt[3]{W}$

Male

FVC	[l]	-11.606+8.172H–0.0339A*H+1.2869ln(A)	0.628
FEV*1,0	[l]	-8.125+6.212H-0.03A*H+0.977ln(A)	0.533
√PEF	[l/s]	1.798+2.311ln(H)+0.0159A-0.000248A2	0.269
√MEF*75%	[l/s]	1.581+1.854ln(H)+0.0213A-0.000283A2	0.300
√MEF*50%	[l/s]	1.490+1.290ln(H)+0.0125A-0.000218A2	0.314
√MEF*25%	[l/s]	1.314+0.898ln(H)-0.0083A-0.000026A2	0.231
FEV*1,0/FVC	[%]	101.99-1.191H2-3.962ln(A)	5.450

Female

FVC	[l]	-10.815+6.640H–0.0408A*H+1.7293ln(A)	0.450
FEV*1,0	[l]	-6.995+5.174H-0.0314A*H+1.0251ln(A)	0.384
√PEF	[l/s]	1.832+1.838ln(H)+0.0078A-0.000172A2	0.236
√MEF*75%	[l/s]	1.779+1.421ln(H)+0.0096A-0.000179A2	0.247
√MEF*50%	[l/s]	1.561+1.177ln(H)+0.0045A-0.000140A2	0.268
√MEF*25%	[l/s]	1.372+0.938ln(H)-0.0152A+0.000036A2	0.212
FEV*1,0/FVC	[%]	118.993-3.032H2-6.9053ln(A)	5.318

Boys

Ln(FVC)	[l]	-1.142+1.259H+0.004070A√W	0.111
Ln(FEV*1,0)	[l]	-1.178+1.221H+0.003841A√W	0.112
Ln(PEF)	[l/s]	-0.214+0.921H+0.0467A+0.0020W	0.150
Ln(MEF*75%)	[l/s]	-0.077+0.770H+0.0373A+0.0025W	0.177
Ln(MEF*50%)	[l/s]	-0.522+0.843H+0.0300A+0.0035W	0.221
Ln(MEF*25%)	[l/s]	-1.576+1.166H+0.0219A+0.0021W	0.291
FEV*1,0/FVC	[%]	101.99-1.191H2-3.962ln(A)	5.450

Girls

Ln(FVC)	[l]	-3.842+4.1632√H+0.1341√A-1.614Fi	0.112
Ln(FEV*1,0)	[l]	-3.877+3.9809√H+0.1485√A-1.322Fi	0.108
Ln(PEF)	[l/s]	0.411+1.793ln(H)+0.4251ln(A)-0.910Fi	0.146
Ln(MEF*75%)	[l/s]	0.455+1.616ln(H)+0.3738ln(A)-0.861Fi	0.164
Ln(MEF*50%)	[l/s]	0.256+1.643ln(H)+0.3481ln(A)-1.089Fi	0.206
Ln(MEF*25%)	[l/s]	-0.772+2.002ln(H)+0.3063ln(A)-0.409Fi	0.284
FEV*1,0/FVC	[%]	92.33	4.850

Sweden National (Hedenström / Malmberg, 1985)

Formula:

Reference value = B1*A + B2*log(A) + B3 / H + C

A: Age - years

H: Height - metre

B1, B2, B3, C: according to the table below:

	B1	B2	B3	C
Woman				
mpFVC	-0.00982	0.6358	-1.4137	0.832
mpFEV10	-0.0092	0.4772	-1.3284	0.9296
mpFEV10IVC	0.00096	-0.2223	0.1233	2.1533
mpFEV10FVC	0.00062	-0.1586	0.0853	2.0975
mpPEF	-0.00677	0.4017	-0.7422	0.9661
mpFEF50	-0.00741	0.3471	-0.8581	0.9336
mpFEF25	-0.01548	0.3431	-0.8498	0.7966
mpPIF	-0.00909	0.6156	-1.1867	0.8731
mpIVC	-0.01016	0.6995	-1.4518	0.7763
Man				
mpFVC	-0.00827	0.586	-1.4468	0.9461
mpFEV10	-0.00587	0.2756	-1.1655	1.098
mpFEV10IVC	0.00246	-0.3553	0.3095	2.1933
mpFEV10FVC	0.0024	-0.3104	0.2813	2.1519
mpPEF	-0.00211	0.1049	-0.6774	1.3255
mpFEF50	-0.00041	-0.3087	-0.148	1.3415
mpFEF25	-0.00771	-0.2819	-0.0252	1.0597
mpPIF	-0.00484	0.2715	-0.9965	1.2709
mpIVC	-0.00833	0.6309	-1.475	0.9047

Finnish National (Viljanen, 1981)

The reference value equals to the sum of the parameters in the header multiplied with the value in the given row.

Smoke Years: Duration of smoking - years

Pack-years: Smoke Years * gram Tobacco / day / 20

	Age²	Age	Height cm	Weight kg	Smoke-years	Tobacco (g/nap)	Pack-years	Age* Pack-years	Constants	RSD
Female										
FEV1		-0.0281	0.0258		-0.0052				0.130	0.400
FEV1/IVC		-0.2371	-0.2809				-0.1694		136.400	6.870
FRC		0.0153	0.0752	-0.0294	0.0094				-8.165	0.510
FRC/TLC		0.2504	0.6059	-0.4536					25.750	6.640
FVC	-0.000118	-0.0143	0.0545						-4.205	0.430
Ln Gaw/V		-0.0019	-0.0068				-0.0008	-0.000170	2.079	0.400
Ln Raw		0.0007					0.0042	0.000023	4.819	0.410
MEF25	0.000768	-0.1013		0.0054	-0.0086				3.970	0.490
MEF50	0.000132	-0.0509		0.0337	-0.0219				4.073	1.090
MEF75	-0.001302	0.0739		0.0339	-0.0121				4.088	1.370
MTT		0.0051	0.0098	-0.0049			0.0041		-0.793	0.230
MVV		-0.7806	0.8124		-0.1368				2.550	13.800
PEF	-0.001206	0.0647		0.0195	-0.0140				6.544	1.260
RV		0.0289	0.0231		0.0100				-3.640	0.440
RV/TLC		0.5094			0.1164				4.320	6.580
TLC			0.0700		0.0100				-6.103	0.580
TLCO	-0.01206	0.0104		0.7517	-0.1492	-1.0101			111.600	20.100
IVC	-0.000145	-0.0119	0.0552						-4.329	0.430
Male										
FEV1	-0.00041	0.01450	0.05090	0.05090	-0.00810				-4.67000	0.46000
FEV1/IVC		-0.22510	-0.12860	-0.12860	-0.05680				109.40000	6.04000
FRC		0.01950	0.11070	-0.04840					-12.78000	0.70000
FRC/TLC		0.17610	0.60170	-0.54150			0.06020		-19.26000	6.01000
FVC	-0.00071	0.04670	0.07440	0.07440	-0.00650				-8.44000	0.61000
Ln Gaw/V		-0.00750	-0.01570	-0.01570	-0.00500				3.90000	0.44000
Ln Raw		0.00290	-0.00980	-0.00980	0.00390				5.47000	0.43000
MEF25	0.00022	-0.05130	0.01930	0.01930	-0.00760				0.19000	0.51000
MEF50	-0.00064	0.02450	0.03750	0.03750	-0.01670				-1.71000	1.15000
MEF75	-0.00051	0.01930	0.06780	0.06780	-0.01730				-3.79000	1.56000
MTT		0.00610	0.00440	0.00440			0.00180		-0.27000	0.15000
MVV		-0.76290	1.55240	1.55240	-0.30450				-102.50000	18.50000
PEF	-0.00034	0.01690	0.08850	0.08850	-0.01390				-5.80000	1.29000
RV		0.02680	0.04980	-0.01810			0.00770		-6.59000	0.46000
RV/TLC		0.32480	0.16850	-0.16710			0.09990		-3.76000	5.16000
TLC		0.01170	0.12340	-0.01720					-13.73000	0.79000
TLCO		-1.01030	1.31490	1.31490			-0.70400		-24.44000	22.20000
IVC	-0.00069	0.04710	0.07520	0.07520	-0.00690				-8.56000	0.62000

APPENDIX II.

Format of the patient identification field

The format of the patient identification filed can be any free text or some predefined format according to a special mask.

If this mask is defined the ID field is compulsory to fill during adding a new patient. Otherwise the field can be left empty.

!	If a ! character appears in the mask, optional characters are represented in the text as leading blanks. If a ! character is not present, optional characters are represented in the text as trailing blanks.
>	If a > character appears in the mask, all characters that follow are in uppercase until the end of the mask or until a < character is encountered.
<	If a < character appears in the mask, all characters that follow are in lowercase until the end of the mask or until a > character is encountered.
<>	If these two characters appear together in a mask, no case checking is done and the data is formatted with the case the user uses to enter the data.
\	The character that follows a \ character is a literal character. Use this character to use any of the mask special characters as a literal in the data.
L	The L character requires an alphabetic character only in this position. For the US, this is A-Z, a-z.
l	The l character permits only an alphabetic character in this position, but doesn't require it.
A	The A character requires an alphanumeric character only in this position. For the US, this is A-Z, a-z, 0-9.
a	The a character permits an alphanumeric character in this position, but doesn't require it.
C	The C character requires an arbitrary character in this position.
c	The c character permits an arbitrary character in this position, but doesn't require it.
0	The 0 character requires a numeric character only in this position.
9	The 9 character permits a numeric character in this position, but doesn't require it.
#	The # character permits a numeric character or a plus or minus sign in this position, but doesn't require it.
:	The : character is used to separate hours, minutes, and seconds in times. If the character that separates hours, minutes, and seconds is different in the regional settings of the Control Panel utility on your computer system, that character is used instead.
/	The / character is used to separate months, days, and years in dates. If the character that separates months, days, and years is different in the regional settings of the Control Panel utility on your computer system, that character is used instead.